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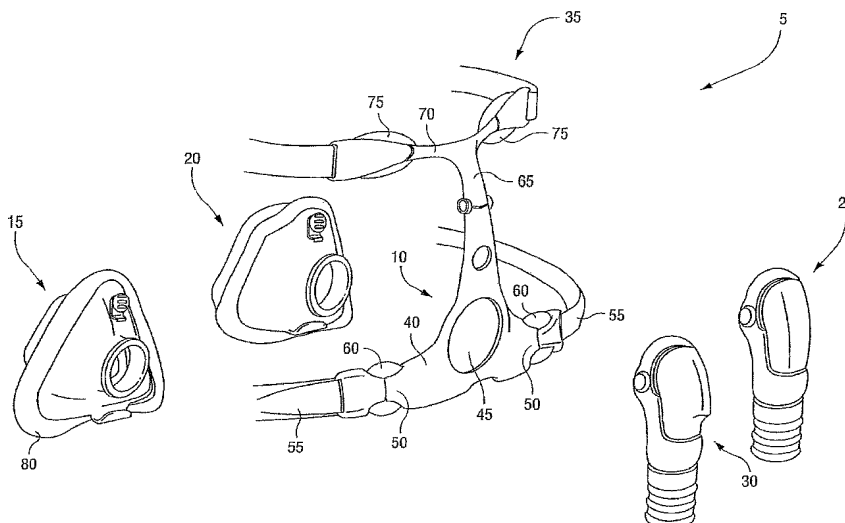
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(54) Title: INTERCHANGEABLE MASK ASSEMBLY



(57) Abstract: A system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components (15, 20), e.g., full-face, nasal, nasal prongs, nose tip, and/or a combination of any of the above, including a nasal or full-face cushion and nasal prongs/nozzles combination, etc., that are different from one another in at least one aspect, and a common frame assembly (10) configured to support each of the first and second cushion components (15, 20). Various embodiments are directed to a full-face or nasal mask used with a frame having lateral connector portions having a stiffening member. The mask assembly may include a nose height adjustment device for the height of the cushion, or a cushion adjustment member by which the position of the cushion may be adjusted relative to the frame. The mask assembly may include a chin strap assembly (620).

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## TITLE OF THE INVENTION

## INTERCHANGEABLE MASK ASSEMBLY.

## CROSS REFERENCE TO APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/729,746, filed October 25, 2005, which is incorporated herein by reference in its entirety.

## FIELD OF THE INVENTION

[0002] The present invention relates to a nasal assembly used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Continuous Positive Airway Pressure (CPAP) or Non-Invasive Positive Pressure Ventilation (NPPV).

## BACKGROUND OF THE INVENTION

[0003] Interfaces, such as a nasal mask assembly, for use with blowers and flow generators in the treatment of sleep disordered breathing (SDB) typically include a soft-face contacting portion, such as a cushion, and a rigid shell or frame. In use, the interface is held in a sealing position by headgear so as to enable a supply of air at positive pressure (e.g. 2-30 cm H<sub>2</sub>O) to be delivered to the user's or patient's or user's airways.

[0004] One factor in the efficacy of therapy and compliance of patients with therapy is the comfort and fit of the patient interface. It has been necessary to design a wide variety of masks to best treat and/or suit the user's needs. While there are a large number of patient interfaces, typically each cushion has been specially designed to be used with only a single frame, headgear, etc.

[0005] Puritan Bennett includes a mask commercially sold under the name of Breeze® that allows a cushion sold under the name of DreamSeal® to be retrofit to it. Further details of such mask are disclosed at the website <http://www.puritanbennett.com/prod/Product.aspx?S1=SPT&S2=&id=233>.

## BRIEF SUMMARY OF THE INVENTION

**[0006]** One aspect of the present invention is to provide a mask assembly including at least one main component that can be used with a variety of different styles or types of mask assemblies.

**[0007]** In one embodiment of the invention, there is provided a system of breathing arrangements for delivering breathable gas to a patient, comprising at least first and second cushion components that are different from one another in at least one aspect, and a common frame assembly configured to support each of the first and second cushion components.

**[0008]** In another embodiment of the invention, there is provided a mask assembly for a user comprising a frame having a main body and lateral connector portions; and a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame, said main wall portion including a stiffening portion.

**[0009]** In another embodiment of the invention, there is provided a mask assembly for a user comprising a frame having a main body and lateral connector portions; and a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame, said frame being configured for positioning beneath the nose and between the user's upper lip and nose in use.

**[0010]** In another embodiment of the invention, a mask assembly for a user comprising a frame having a main body and lateral connector portions; a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame, said cushion having an upper portion and a lower portion, wherein at least the upper portion includes a nose height adjusting member.

**[0011]** In another embodiment of the invention, there is provided a mask assembly for a user comprising a frame; a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame; and a frame adjustment member to adjust the position of the cushion component relative to the frame.

**[0012]** In another embodiment of the invention, there is provided a mask assembly for a user comprising a frame; a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use and a main wall portion, opposite from the aperture, extending upwardly away from the frame; and a chin strap assembly including an extension member provided to each side of the frame and a chin strap having a main chin support portion and straps coupled to the extension members.

[0013] In another embodiment of the invention, there is provided a mask assembly for a user comprising a common frame; a cushion component provided to the frame and including a pair of nasal prongs or nozzles adapted to engage the user's nares in use; and a supplemental cushion component in the form of a nasal cushion or a full-face cushion, wherein the cushion component and the supplemental cushion component cooperatively seal with the user's face in use.

[0014] These and other aspects of the invention will be described in or apparent from the following detailed description of embodiments.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Preferred embodiments of the invention will be described in relation to the following figures, in which:

[0016] Fig. 1 is a schematic view of a mask assembly according to an embodiment of the present invention;

[0017] Figs. 2-13 are views of a mask assembly according to another embodiment of the present invention;

[0018] Fig. 14 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0019] Figs. 15-16 are views of a mask assembly according to yet another embodiment of the present invention;

[0020] Figs. 17-19 are views of a portion of a mask assembly according to still another embodiment of the present invention;

[0021] Fig. 20 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0022] Fig. 21 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0023] Fig. 22 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0024] Fig. 23 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0025] Fig. 24 is a perspective view of a mask assembly according to another embodiment of the present invention;

[0026] Figs. 25-26 are views of a mask assembly according to another embodiment of the present invention; and

[0027] Figs. 27-31 are views of a mask assembly according to still another embodiment of the present invention.

## DETAILED DESCRIPTION OF EMBODIMENTS

[0028] The following description is provided in relation to several embodiments which may share common characteristics and/or features. It is understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments which combinations form additional embodiments.

### 1.0 First Embodiment – Common Frame with Aactiva™ or UltraMirage™ Cushion Component

[0029] Fig. 1 illustrates an interchangeable mask system 5 according to an embodiment of the present invention. Mask system includes a common frame component 10, one of two cushion components 15, 20, one of two elbow components 25, 30, and headgear 35. The mask system is intended for use in positive pressure therapy for users with obstructive sleep apnea (OSA) or another respiratory disorder.

[0030] The common frame 10 has a main body 40 defining a central opening 45. Main body 40 includes at least two lateral arms 50, each of which can be coupled to a headgear strap 55 of headgear. The straps may be connected to the frame using a press-fit connector 60, as is known in the art. Common frame 10 may also include a forehead support 65 that has a bridge 70 provided with forehead pads 75 to rest against the user's forehead in use. Forehead support may be adjustably mounted to the common frame, in a manner known in the art.

[0031] Common frame 10 is configured to be selectively coupled to one of cushion components 15, 20 and to one of elbow components 25, 30. Cushion components 15, 20 differ in at least one respect such that one may be more optimal or preferable for use with one user, while another may be more suitable or preferably for use with another user. For example, cushion component 15 may be an Activa™ component, while cushion component 20 may be an UltraMirage™ Series II cushion component, both available from ResMed. These cushion components can be significantly different from one another, e.g., the Activa™ includes a gusset portion 80 and a cushion clip assembly (not shown) which is not incorporated in the UltraMirage™ cushion design.

[0032] Common frame 10 is also configured for use with either elbow component 25, or elbow component 30. Elbow components differ in at least one respect, e.g., each may include gas washout vents that are configured for predetermined washout rates, noise, etc.

[0033] Common frame 10 is advantageous since it works with a plurality of different cushion components, elbow components, forehead supports, etc., thereby eliminating the need to specifically make the frame for a particular peripheral component, as is the standard.

## 2.0 Second Embodiment – Common SWIFT™ Frame with VISTA™ Cushion Component – Below the Nose

[0034] Figs. 2-13 show a mask system 90 according to another embodiment of the present invention. As shown in Fig. 2, mask system 90 includes a common frame 95, a cushion component 100 and a common headgear assembly 105.

[0035] Common frame is similar to ResMed's SWIFT™ frame, described in more detail in relation to U.S. Patent Application no. 10/781,929, filed February 20, 2004, incorporated herein by reference in its entirety. As shown in Fig. 3, common frame includes a main body 110 including two lateral connectors 115. Each lateral connector 115 is provided with a seal portion 120 (Fig. 4). Each seal portion 120 has a channel 125 structured to receive and support a ring shaped portion 130 of a yoke 135 of the headgear assembly 105. Each seal portion 120 also includes an aperture 140 to receive either an



elbow 145 or a plug 150. In an alternative, each seal portion 120 may receive an elbow 145, i.e., receive two sources of gas (without the plug).

**[0036]** Fig. 3 is an exploded view of cushion component 100, frame 95 and a clip element 175, together defining a cushion sub-assembly 155. Fig. 4 shows the cushion sub-assembly 155 in the assembled condition, along with yoke 135, seal portion 120 and elbow 145. Fig. 5 is a cross sectional view of the assembly. Figs. 6-10 are additional views of the cushion assembly as assembled with lateral headgear straps and associated yokes.

**[0037]** Cushion component 100 includes lateral sides 160 configured to engage with corresponding channels 165 formed in the frame 95. Cushion component 100 includes an aperture 196 (schematically illustrated) to receive the user's nose. End portions 170 of cushion component 100 are wrapped around frame 95, and clip element 175 is attached to the sub-assembly of the cushion component and the frame, by sliding the clip element over the combined cushion component and frame. Figs. 4 and 13 are a cross-sectional view showing the sandwich-like connection between the lateral sides of the cushion 170, the frame 95 and the clip element 175.

**[0038]** Fig. 11 is a top view of the mask assembly in use on a user's head, while Fig. 12 is a front view. As seen, common frame 95 is positioned just below and partially under the user's nose, and above the upper lip of the user. This positioning of the frame to cushion interface closer to the centroid of the mask assembly, which helps keep a low profile (non-obstructive) and reduces moments imposed on the mask assembly tending to pull the mask assembly away from the user's face.

**[0039]** In the embodiment described above, the cushion component 100 is bisected (see Figs. 4 and 13) along the longitudinal axis of the frame to create later sides that wrap around the frame for insertion of the channel. In another embodiment, the cushion is not necessarily bisected. Instead, the apertures in the lateral sides of the cushion are simply stretched over the connectors of the frame until a protruding portion of the cushion engages the respective channels of the frame.

[0040] Further, cushion component 100 has an upper portion 200 that is configured to contact the transition between the bony and cartilage portions of the user's nose. Generally, with regard to its footprint, the cushion component is similar to ResMed's VISTA™ cushion, as described in U.S. Patent application no. 11/124,251, filed May 9, 2005, incorporated herein by reference.

[0041] Cushion component 100 has a thickened portion 205 that acts as a pseudo or "soft" frame to provide support for the rest of the membrane of the cushion. Effectively, the thickened portion 205 of the cushion enlarges the "frame" area of the common Swift™ frame. In this example, the thickened portion 205 has the shape of a semi-circle or trapezoid. See, e.g., Figs. 2 and 12.

[0042] Common headgear assembly 105 is similar to the headgear assembly described in relation to ResMed's U.S. Patent application no. 10/781,929. However, common headgear 105 has some differences. For example, as shown in Fig. 13, the vectors of the headgear straps 210 are changed.

[0043] In Figs. 6-13, the elbow 145 is omitted for clarity, although the plug 150 is illustrated. As shown in Figs. 3, 7-8, and 11, the mask assembly includes a gas washout vent 215. The vent 215 could be on the frame and/or the cushion component. As shown in Fig. 8, the yoke 130 includes an alignment indicator 220 that aligns with one of a corresponding array of indicators 225 on the cushion/frame subassembly. The cushion/frame subassembly is rotatable relative to the headgear to ensure proper fit.

### 3.0 Third Embodiment – Common Swift™ Frame with Mirage™ Cushion Component

[0044] Fig. 14 illustrates a mask assembly 230 include a common frame 235, a headgear assembly 240 and a cushion component 245. This embodiment is similar to the prior embodiment, especially as the common frame is the same as described above in relation to Figs. 2-13. The main difference is that the cushion component 245 takes the form of a nasal mask, e.g., ResMed's Mirage™ type cushion, as described in U.S. Patent No. 6,112,746, incorporated herein by reference in its entirety. In this embodiment, the cushion component 245 is configured to form a breathing cavity that surrounds the nose

of the user. The cushion component includes an upper apex portion 250 that makes contact with the bridge of the user's nose, between the eyes.

[0045] The cushion component 250 may include a thickened section 255 in order to help prevent flopping of the cushion away from the user's face. The thickened section 255 may include a cutout 260 in each corner to reduce force on the nasal bridge region.

#### 4.0 Fourth Embodiment – Common Swift™ Frame with Vista™ Cushion Component – Over the nose

[0046] Figs. 15-16 show a mask assembly 275 according to another embodiment of the present invention. Mask assembly 275 includes a common frame 280, a headgear assembly 285, and a cushion component 290 like that described in relation to Figs. 2-13 above. One difference in the present embodiment is the positioning of the common frame 280 relative to the user's face/nose. Specifically, the common frame 280 is positioned above the lower portion of the user's nose, such that the tip of the nose extends below the clip element 295. Further, as shown in Fig. 16, the vectors formed by the headgear straps 300 are slightly different than as shown in described in relation to Fig. 13. As a result of the positioning of the frame/cushion interface to more centrally locate the frame relative to the cushion, and/or because the vectors from the headgear straps act closer to the centroid of the mask on the face, this design may not necessarily include a thickened portion of the cushion.

#### 5.0 Fifth Embodiment – Vista/Swift Prongs Combination

[0047] Figs. 17-19 show a portion of another mask assembly 305 according to an embodiment of the present invention. Fig. 17 shows a common Swift™ frame and cushion assembly 310 in isolation, including prong elements 315 for engagement with the user's nares. Fig. 18 shows a supplemental Vista™ style cushion 320 adapted for use with the Swift™ cushion/frame assembly 310. The mask assembly is supported on the user's head using a headgear assembly as described above.

[0048] The supplemental cushion 320 includes at least one hole 325 provided on its lateral side for insertion over the frame/cushion assembly 310. Supplemental cushion

320 also includes a centrally located hole 330 that aligns with the gas washout vents 335 of the frame/cushion assembly 310. Fig. 19 shows the frame/cushion assembly 310 and the supplemental cushion 320 in assembled form. To assemble the supplemental cushion over the frame, each hole 325 of the supplemental cushion 320 is stretched over the connector of the frame, and the resiliency of the material of the supplemental cushion allows it to engage with the channels of the frame and/or to simply seal with an exposed surface of the frame cushion assembly. In this position, the prongs 315 seal with the nares, while the supplemental cushion includes a face contacting portion that seals with the user's face.

## 6.0 Additional Embodiments

**[0049]** As can be determined from the description above in relation to the embodiments of Figs. 2-13 and the embodiment of Figs. 15-16, one aspect of the invention is directed to the combination of a Swift™ frame with a Vista™ cushion component. As can be appreciated, the combination of these dissimilar mask systems required a number of adjustments, as can be derived from the above description and the drawings.

### 6.1 Locked Elbow

**[0050]** Furthermore, there are additional factors that may be considered when combining the various mask systems. For example, the force due to air pressure against the cushion may cause moments about the elbow. If these moments are not counteracted, the result may be the cushion rotating and losing seal. The elbow should be stiff enough to prevent rotation under pressure. A locking or ratcheting mechanism may be implemented to lock the rotation on the elbow when the desired angle is found. Locking may be achieved using an interference fit, and/or locking components, such as detents or a pin/groove arrangement. Generally, an approximation of the desired effect can be achieved by simply fixing the elbow in place relative to the frame. Otherwise, simply inhibiting rotation, e.g., by strapping the elbow to the adjacent headgear, can be effective as well.

## 6.2 Stiffening Member For Cushion Component

**[0051]** When the cushion is under pressure, moments about the cushion to frame interface are created. The force vector points which cause the moments may be shifted by introducing a non-flexible or stiffening member to the cushion. That is to say, in addition to having a moment about the elbow, there is also a moment about the interface of the stiff section of the cushion and the flexible part of the cushion.

### 6.2.1 Stiffening Ribs

**[0052]** The mask assembly 340 in Fig. 20 includes a cushion component 345 that is similar in general shape to the Vista<sup>™</sup> cushion in terms of its intended sealing footprint relative to the user's face, but it includes a plurality of ribs 350 that extend from the clip element 355 to the top of the cushion, to stop or help prevent the cushion from flexing about the elbow (or flopping off the face). The stiffening member (ribs in this example) will move this vector away from the elbow, and prevent the cushion from flopping off the face. The stiffening member should extend as close to the skin as possible without compromising comfort. The common frame is similar to that described above and may be, e.g., a Swift<sup>™</sup> frame.

**[0053]** The mask assembly 360 in Fig. 21 includes a rib 365 along the perimeter of the cushion to help support and/or push the cushion onto the user's face. The rib 365 may be comolded with the cushion. The cushion forms a breathing cavity which receives the nose of the user, and the upper apex of the cushion extends across the bridge of the user, between the eyes. In this example, the cushion can be ResMed's Mirage<sup>™</sup> cushion, adapted for assembly to common frame. Common frame is similar to that described above and may be, e.g., a Swift<sup>™</sup> frame. However, the clip element 370 of the cushion assembly is slightly rotated such that it is positioned to face downwardly.

### 6.2.2 Thickened Cushion Portion

**[0054]** The stiffening member may take the form of one or more thickened elements, e.g., by thickening the cushion which will result in it being stiffer in sections. See, e.g., the relatively thickened portion of cushion component in Fig. 13. Ribs could be

made in the cushions, extending from the frame to the highest point of the cushion. A pseudo frame could be implemented where a large portion of the cushion is thick silicone, only the areas in contact, or requiring flex (as in a "bubble" cushion or single walled membrane) will be thin.

### 6.3 Nose Tip Cushion Component

**[0055]** Fig. 22 shows a mask assembly 380 according to another embodiment of the invention having a headgear assembly 385 and a common Swift™ frame 390 as described above, as well as cushion component 395 in the form of a nose tip cushion. The cushion includes a membrane that extends up the side of the nose. The membrane could extend just over the tip of the nose. The cushion could incorporate a bubble style seal over the tip of the nose. The mask assembly includes one or more vent openings 400 provided in the frame/cushion component.

### 6.4 Full-Face Cushion

**[0056]** Fig. 23 shows a mask assembly 405 according to yet another embodiment of the present invention having a headgear assembly 410 and common Swift™ frame 415 as described above, as well as a cushion component 420 in the form of a full-face cushion, such as that available from ResMed under the name UltraMirage™ full-face cushion and described in U.S. Patent no. 6,513,526, incorporated herein by reference in its entirety. The cushion component 420 would be adapted for use with a Swift™ type frame, as described above.

**[0057]** The cushion 420 may include a rib 425 that extends from the bottom to the top of the cushion. Furthermore, the frame 415 is positioned on the upper ½ to upper 1/3 of the cushion to support the cushion. The frame to cushion interface is positioned below the nose, although it may be above the nose. The cushion may include one or more gas washout vents 430.

## 7.0 Adjustable Positioning of the Cushion

### 7.1 Adjustable Nose Height

**[0058]** Fig. 24 shows a mask assembly 440 according to yet another embodiment of the present invention including a common Swift™ frame 445, a headgear assembly 450, and a Vista™-like cushion 455 supported by the frame.

**[0059]** The upper part 460 of the cushion may include a thin membrane (the lower cushion may be like a double wall Vista™ cushion). This has the advantage of reduced weight and subjectively feels light to wear. It may also allow deflection around contours of nose as it will be more flexible than a conventional thick cushion. This will help with fit and the range of patients suited to each size.

**[0060]** In an alternative, the upper part 460 of the cushion shown in Fig. 24 includes a bellows type arrangement around the cushion which may be inflated to help pressure and fit, like the ResMed Activa™ mask, described in U.S. Patent No. 4,772,760 and U.S. application no. 10/655,622, filed September 5, 2003, each incorporated herein by reference in its entirety. In the alternative, the cushion may include a stiff drinking straw-like structure, e.g., plastic corrugations that maintain shape in a variety of positions. The straw-like structure would click or fold into different positions to allow more or less nose height.

**[0061]** The lower part of the cushion 465 may include a gusset portion, a double gusset, or a solid silicon structure.

### 7.2 Adjustable Cushion Height

**[0062]** As described above, the position of the centroid of the cushion to frame interface (frame clip location) may be changed, depending on application. The closer the headgear vectors act to the centroid of the cushion the more stable the cushion will be on the face of the patient; this can reduce the rigidity required within the cushion to maintain support of the membrane. The frame location in Figs. 2-13 is closer to the centroid as compared to the location of the centroid in Figs. 15-16. In these embodiments, the positions of the cushions relative to the face remain generally constant.

[0063] However, it is also possible to change the position of the cushion relative to the face and frame, while maintaining the frame in a constant position. The mask assembly 500 in Figs. 25 -26 includes a common Swift™ frame 505 supported by Swift™-like headgear 510, in addition to a Vista™ like cushion 515 supported by the frame 505.

[0064] In Figs. 25-26, the axis of location of the frame 505 is across the middle of the nose, although it could be higher or lower. As schematically shown, the axis of location of the frame onto the cushion may vary according to user preference (which will be influenced by head shape/headgear angles). In Figs. 25-26, it can be seen that the headgear-frame angle remains constant and the frame is located at higher or lower cushion positions, position 2 in Fig. 25 and position 3 in Fig. 26. Adjustment can be effected using mechanical expedients such as a sliding arrangement. Holes in the sides of the cushion may allow stretching in to accommodate positioning of the cushion in the various positions.

[0065] Alternatively, the headgear and frame angle may rotate around the same cushion position. As a further alternative the headgear location point could be on a lobe or cam to move it relative to the cushion. A further embodiment is the use of weight to change the center of gravity of the cushion or frame/headgear system.

## 8.0 Chin Strap

[0066] Figs. 27-31 illustrate a mask assembly 600 according to a further embodiment of the present invention. Mask assembly includes a frame 605 (e.g. polycarbonate shell), a headgear assembly 610, a cushion component 615, and a chin strap assembly 620 supported by the frame.

[0067] Chin strap assembly 620 includes an extender 625 and chin strap 630. Extender 625 is shown in Fig. 30 and is preferably made of a rigid material, e.g., polycarbonate or a rigid plastic backed with headgear foam material. Extender 625 includes an aperture 635 by which a bevel clip 640 (Fig. 29) may be used to selectively attach the extender 625 to the frame, e.g., using interference snap fit. Extender 625 includes a hole 640 for receiving a strap 645 of the chin strap. Each strap includes hook and loop fastening elements, e.g., Velcro®.



**[0068]** Chin strap 630 includes a cushion sealing area 650, and is made from a foamed headgear material. The chin strap is preferably elastic. Chin strap is bonded to the frame at a bond point or region 655, e.g., as shown in Figs. 27, 28 and 31. Bonding may be achieved, e.g., via adhesive, plasma or lamination methods.

**[0069]** Another variant is to simply use only the extender and chin strap shown in Figs. 30 and 31, respectively, along with another mask of choice, e.g., ResMed's Nightingale mask, more fully described in PCT Patent application no. PCT/AU04/01832, filed December 24, 2004, incorporated by reference in its entirety. A further embodiment is the use of the Nightingale headgear with the chin strap assembly and the frame cushion.

**[0070]** A further embodiment is the combination the full-face seal as shown in Fig 27, along with nasal prongs as shown in Fig. 19.

**[0071]** While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, barriatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

## WHAT IS CLAIMED IS:

1. A system of breathing arrangements for delivering breathable gas to a patient, comprising:  
at least first and second cushion components that are different from one another in at least one aspect, and  
a common frame assembly configured to support each of the first and second cushion components.
2. The system of claim 1, wherein the common frame assembly includes a frame member having a main body and first and second lateral ends each provided with a connector portion.
3. The system of any one of claims 1-2, further comprising an elbow provided to one of the connector portions and a plug provided to the other connector portion.
4. The system of claim 3, wherein the positions of the plug and the elbow are interchangeable.
5. The system of any one of claims 1-2, further comprising first and second elbows provided to the first and second connector portions, respectively.
6. The system of any one of claims 3-5, wherein each said elbow is structured to deliver a supply of pressurized breathable gas to the common frame.
7. The system of any one of claims 3-6, wherein each of the first and second lateral ends of the frame is provided with a seal portion to support each said elbow and/or said plug.

8. The system of any one of claims 1-7, further comprising a headgear assembly having lateral strap portions, each said strap portion having a yoke, wherein each said seal portion includes a channel to support the yoke.

9. The system of any one of claims 2-8, wherein the frame member includes a channel portion provided adjacent each of the first and second ends, wherein each of the first and second cushion components includes a lateral edge that interfaces with the channel portion.

10. The system of any one of claims 1-9, wherein at least one of the first and second cushion components includes a bisected lateral side that is wrapped around the frame.

11. The system of claim 10, further comprising a clip element to secure the bisected lateral sides of each of the cushion components to the frame.

12. The system of any one of claims 1-9, wherein at least one of the first and second cushion components includes an aperture on each lateral side thereof, each said aperture being sized to be stretched over the connector portion and configured to form a seal with a portion of the common frame.

13. The system of any one of claims 1-12, wherein the first and second component are selected from the group including a full-face cushion component, a nasal cushion component, a nose tip cushion component, a nasal prongs component, and a combination of a nasal prongs component and a nasal or full-face cushion component.

14. The system of any one of claims 1-13, further comprising a common headgear assembly which interfaces with the common frame assembly and each of the first and second cushion components.

15. A mask assembly for a user comprising:  
a frame having a main body and lateral connector portions; and  
a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use,

said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame, said main wall portion including a stiffening portion.

16. The assembly of claim 15, wherein said stiffening portion comprises a thickened portion.

17. The assembly claim 16, wherein the thickened portion has a generally semi-circular or trapezoidal shape.

18. The assembly of any one of claims 15-17, wherein the stiffening portion comprises one or more ribs that extend to the top of the cushion component.

19. The assembly of any one of claims 15-18, wherein the stiffening portion includes a rib that generally follows at least a portion of a perimeter of the aperture of the cushion component.

20. The assembly of any one of claims 15-19, further comprising headgear to support the frame and cushion component, wherein the frame and cushion component are rotatable relative to the headgear assembly.

21. The assembly of any one of claims 15-20, wherein the first and second component are selected from the group including a full-face cushion component, a nasal cushion component, a nose tip cushion component, a nasal prongs component, and a combination of a nasal prongs component and a nasal or full-face cushion component.

22. A mask assembly for a user comprising:  
a frame having a main body and lateral connector portions; and  
a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use,  
said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame,  
said frame being configured for positioning beneath the nose and between the user's upper lip and nose in use.

23. The assembly of claim 22, further comprising a headgear assembly including lateral straps extending from the frame in a generally lateral direction.

24. A mask assembly for a user comprising:  
a frame having a main body and lateral connector portions;  
a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion

component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use,

said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame,

said cushion having an upper portion and a lower portion, wherein at least the upper portion includes a nose height adjusting member.

25. The assembly of claim 24, wherein the height adjusting member includes a straw like bellows that can be adjusted to a plurality of predetermined nose heights.

26. The assembly of any one of claims 24-25, wherein the lower portion includes a gusset, a double-gusset, or a solid silicon member.

27. A mask assembly for a user comprising:  
a frame;

a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use, and a main wall portion, opposite from the aperture, extending upwardly away from the frame; and

a frame adjustment member to adjust the position of the cushion component relative to the frame.

28. The assembly of claim 27, wherein the cushion is linearly adjustable relative to the frame.

29. The assembly of any one of claims 27-28, wherein the cushion component is slidable relative to the frame.

30. The assembly of any one of claims 27-28, wherein the cushion includes a hole on each side to accommodate the frame, wherein the hole is formed of elastic material to allow said adjustment while maintaining a seal with the frame.

31. The assembly of any one of claims 27-30, wherein the cushion component is movable to two or more discrete predetermined positions.

32. The assembly of claim 31, wherein the positions are detented or ratcheted.

33. The assembly of any one of claims 27-32, wherein the frame remains substantially stationary relative to the user's face in use during adjustment of the cushion component.

34. A mask assembly for a user comprising:

a frame;

a cushion component provided to the frame and defining a breathing cavity configured to accommodate at least a portion of the user's nose in use, said cushion component including a face contacting seal portion adapted to sealingly engage with at least a portion of the user's nose in use, said cushion component having an aperture to communicate pressurized gas from the breathing chamber to the user's airways in use and a main wall portion, opposite from the aperture, extending upwardly away from the frame; and

a chin strap assembly including an extension member provided to each side of the frame and a chin strap having a main chin support portion and straps coupled to the extension members.

35. The assembly of claim 34, wherein the chin strap includes at least one portion bonded to a portion of the frame or cushion component.

36. The assembly of claim 35, wherein the at least one portion of the chin strap is bonded by adhesive bonding, lamination or plasma bonding.

37. A mask assembly for a user comprising:  
a common frame;  
a cushion component provided to the frame and including a pair of nasal prongs or nozzles adapted to engage the user's nares in use; and  
a supplemental cushion component in the form of a nasal cushion or a full-face cushion,  
wherein the cushion component and the supplemental cushion component cooperatively seal with the user's face in use.

38. The assembly of claim 37, wherein the cushion and the frame form a sub-assembly, and the supplemental cushion is assembled to the sub-assembly.

39. The assembly of claim 38, wherein the supplemental cushion includes at least one lateral hole to receive the sub-assembly, the hole being sized to sealingly engage with a portion of the frame and/or cushion.

40. The assembly of any one of claims 37-39, wherein the supplemental cushion includes one centrally located hole that aligns with at least one vent hole formed in the sub-assembly.

41. A method of designing a series of breathing arrangements for delivering breathable gas to a patient, comprising:



providing at least first and second cushion components that are different from one another in at least one aspect, and

providing a common frame assembly that is connectable with each of the first and second cushion components.

42. The method of claim 41, further comprising providing a common headgear assembly which interfaces with the common frame assembly and each of the first and second cushion components.

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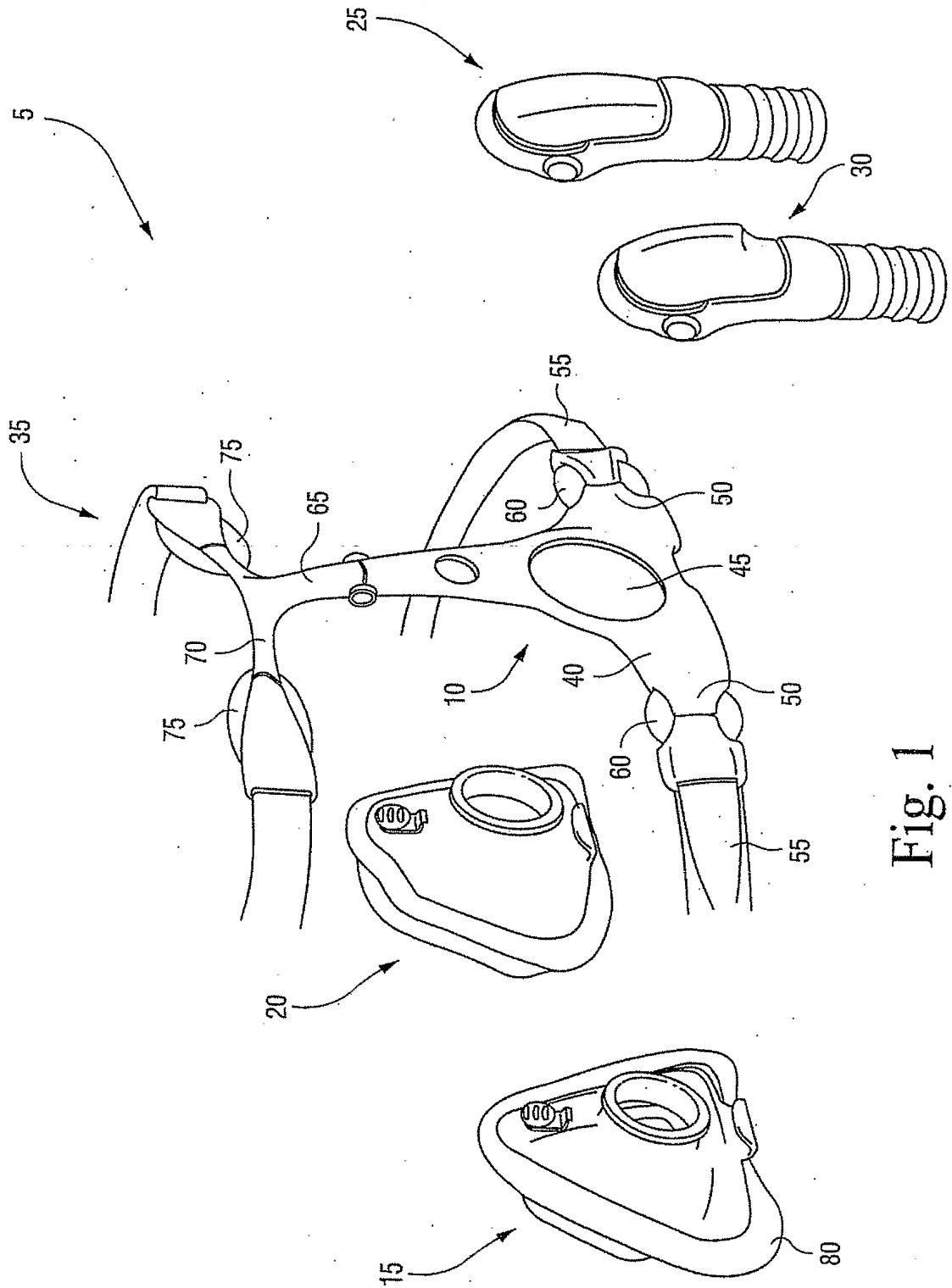


Fig. 1

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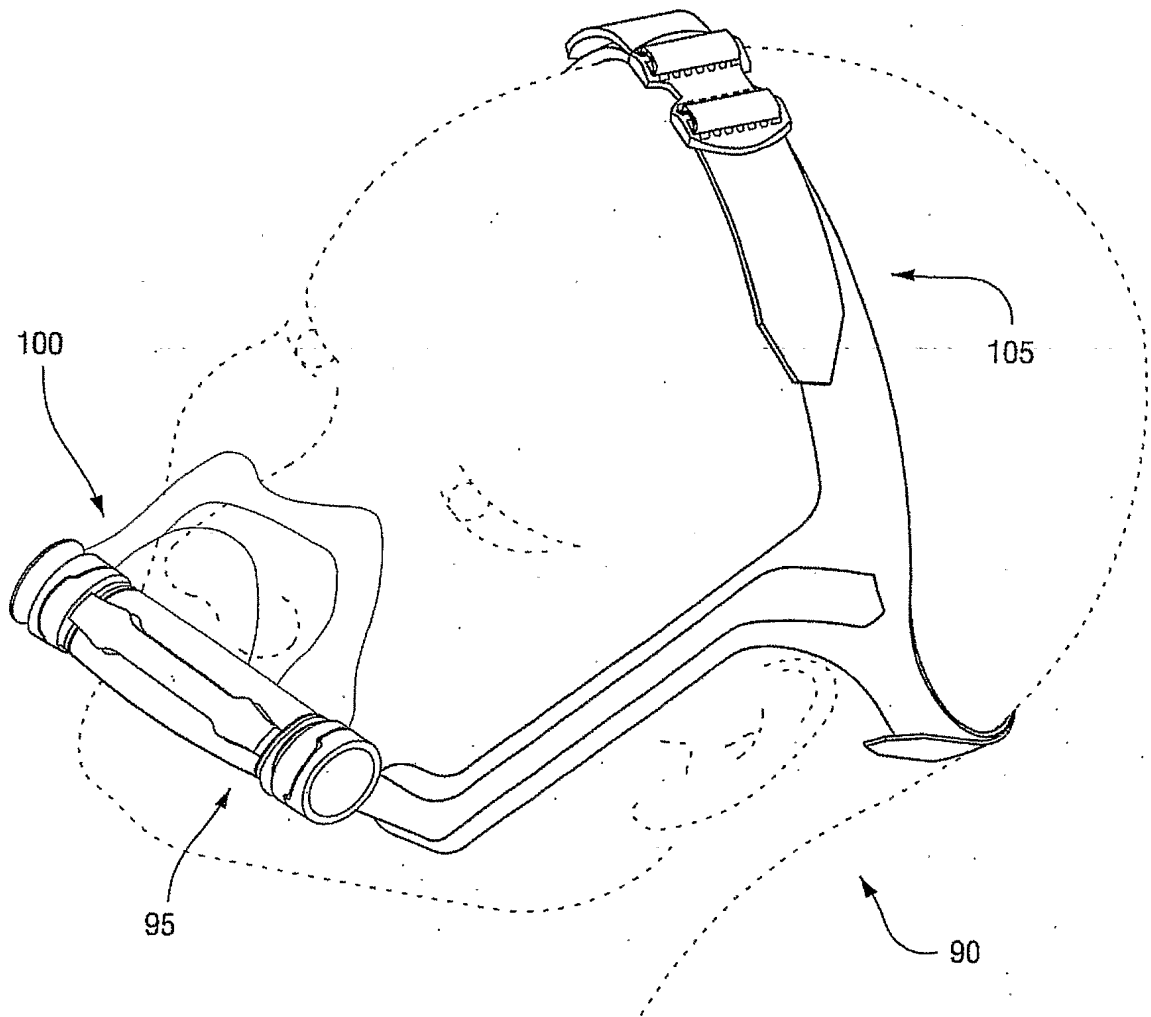


Fig. 2

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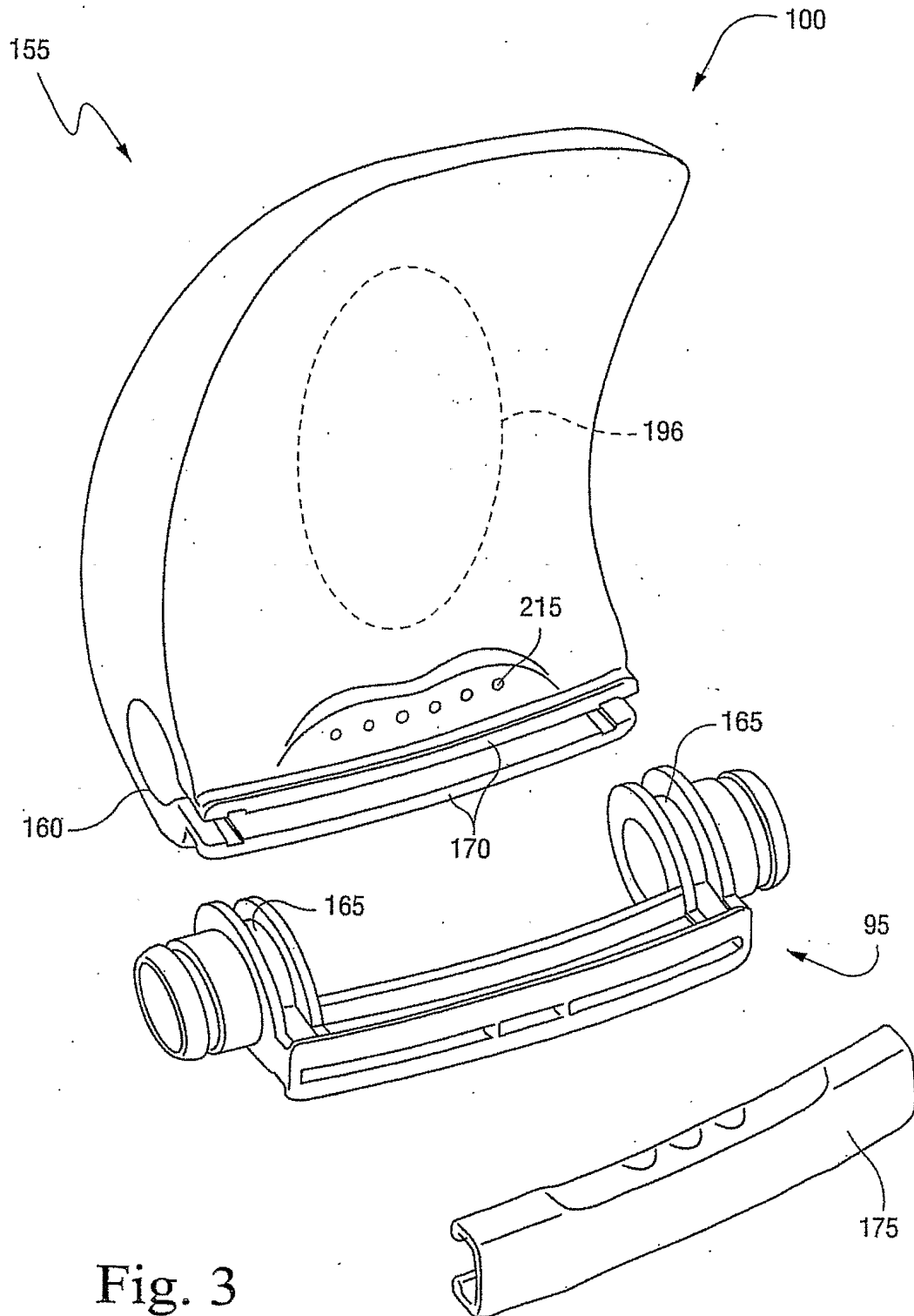
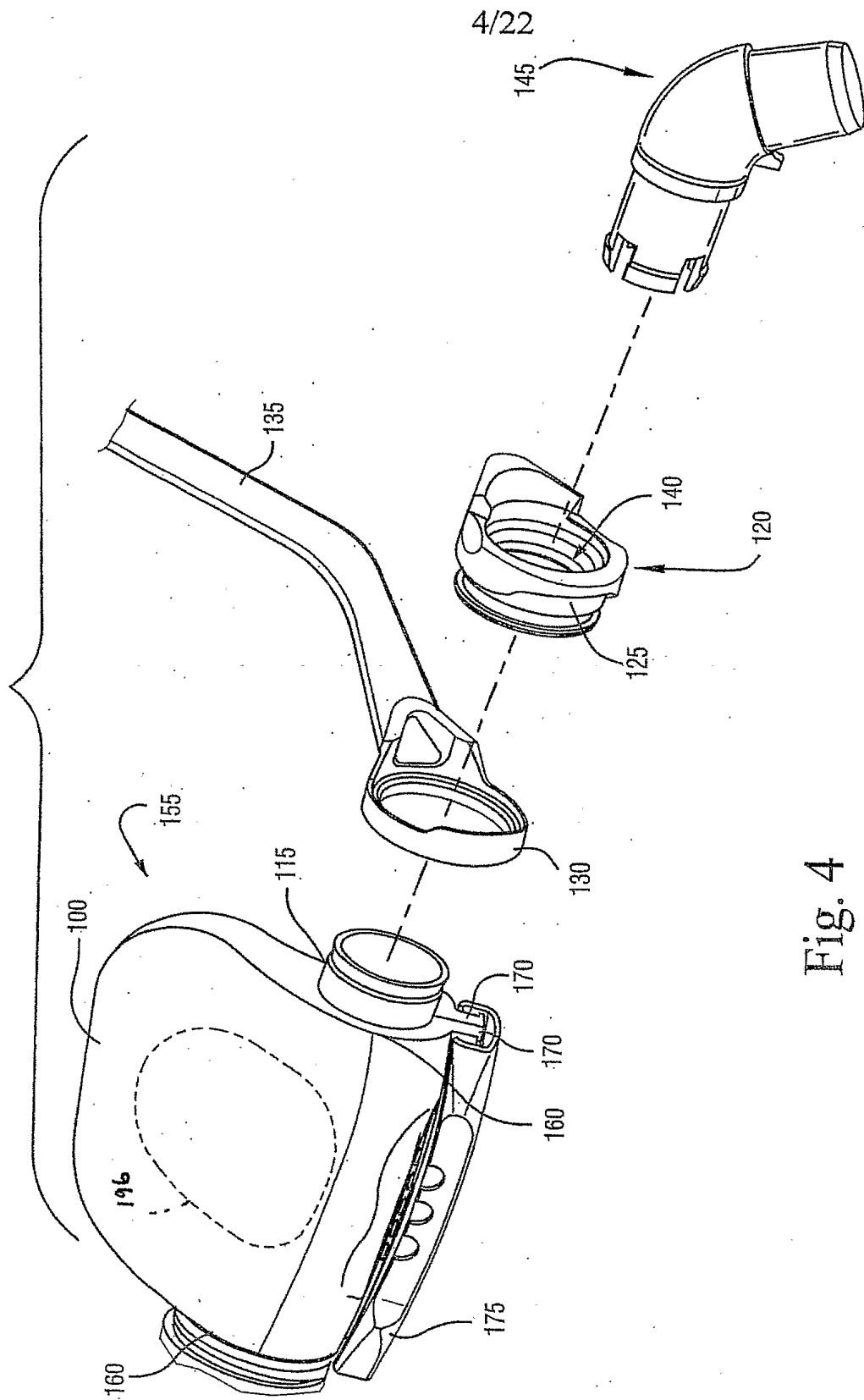


Fig. 3



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L. 50

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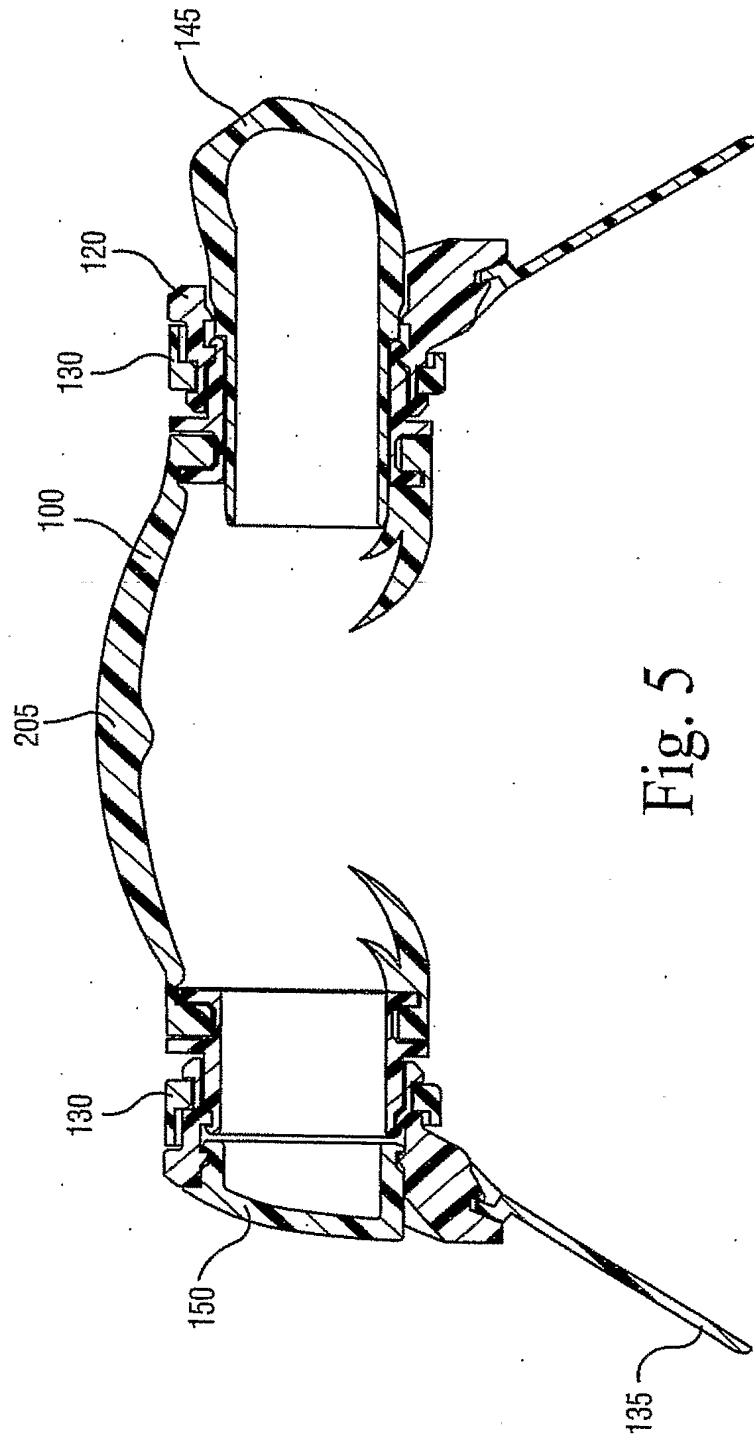


Fig. 5

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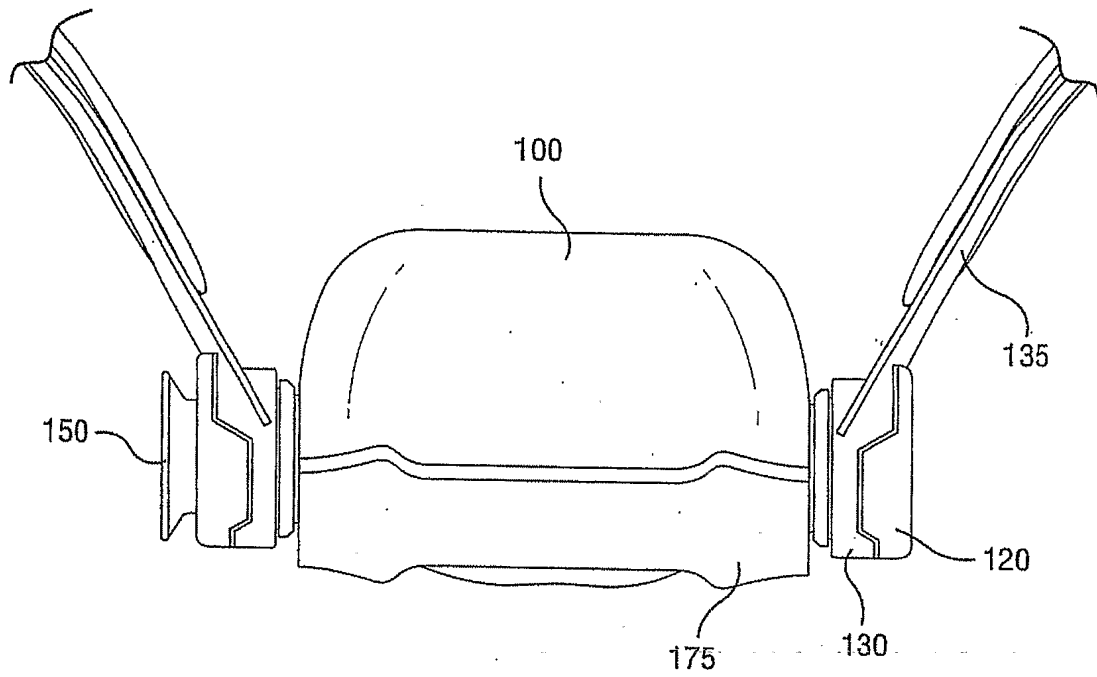


Fig. 6

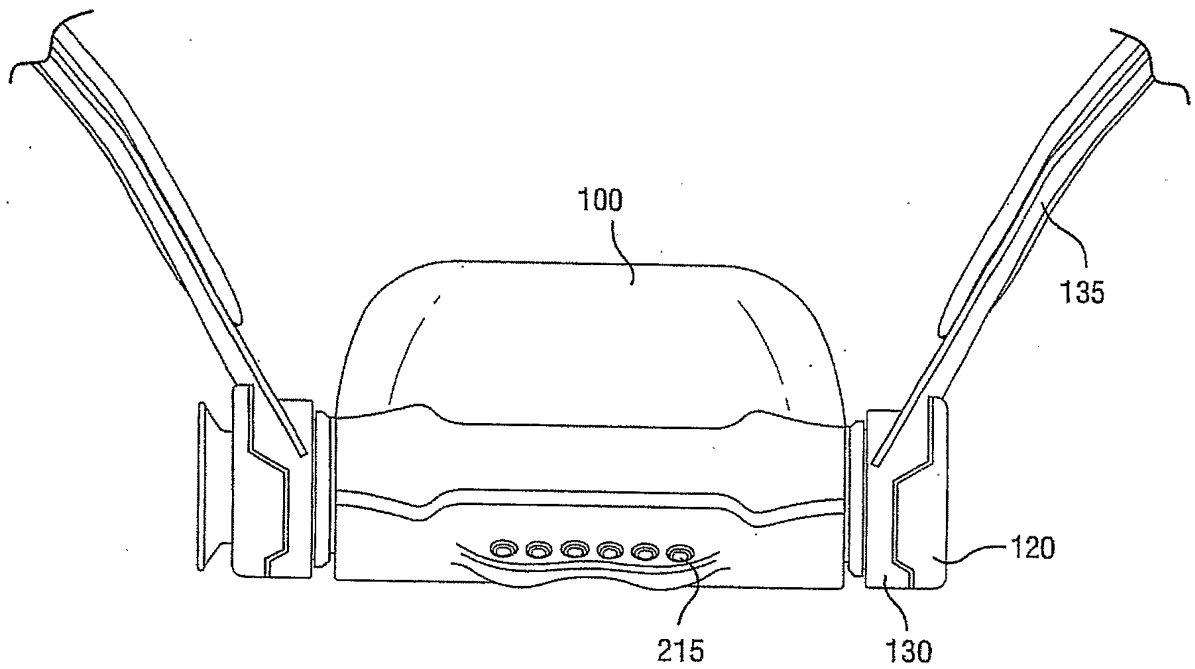


Fig. 7

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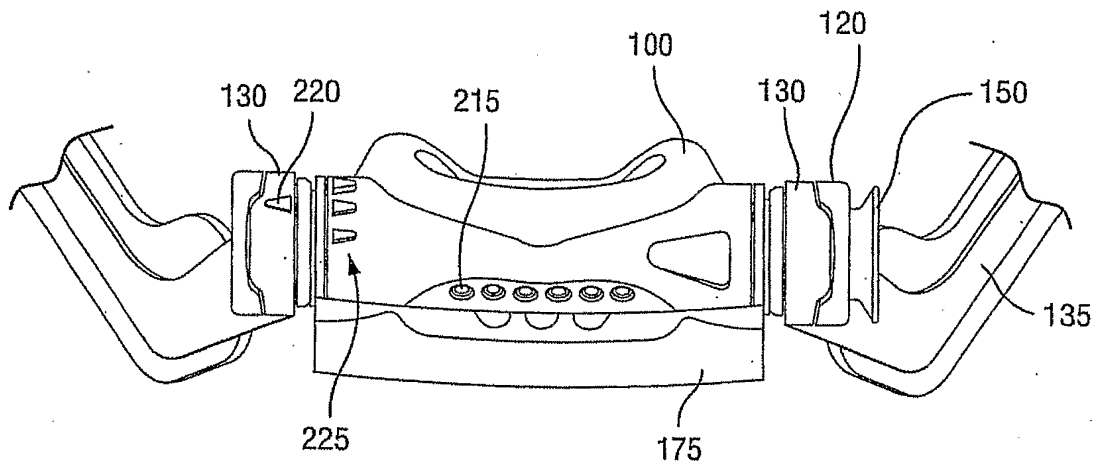


Fig. 8

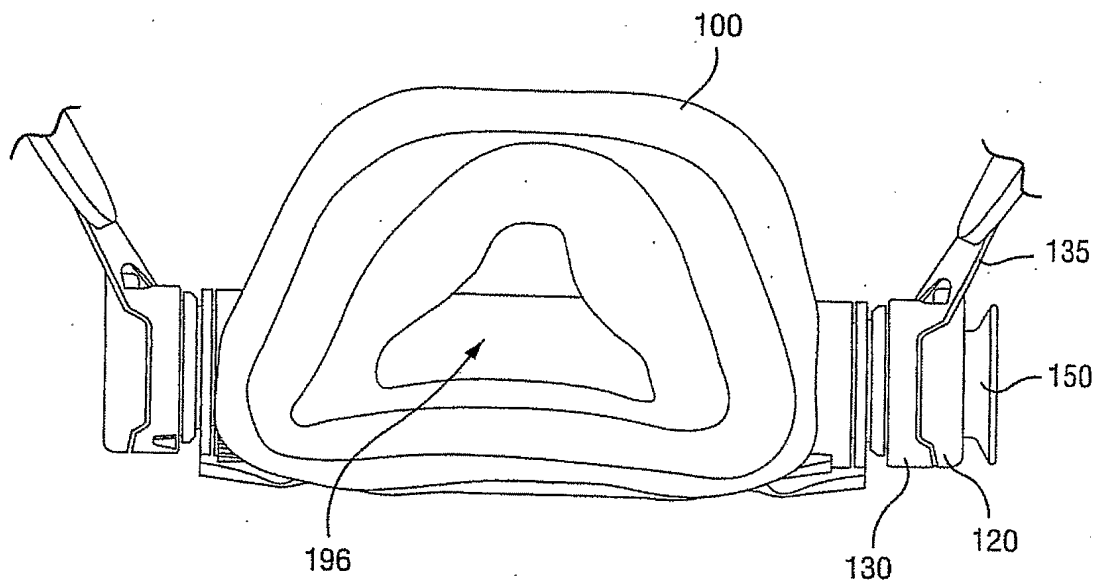


Fig. 9



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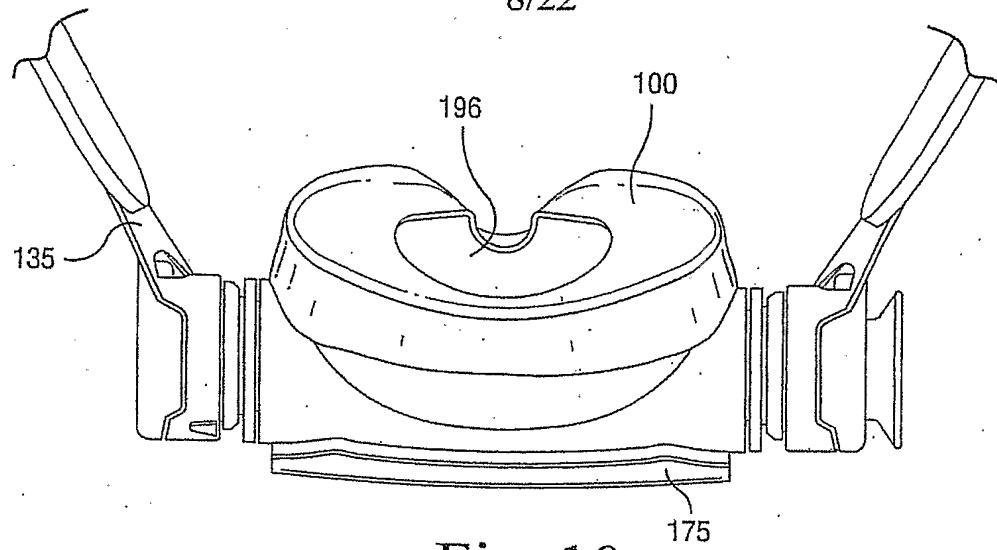


Fig. 10

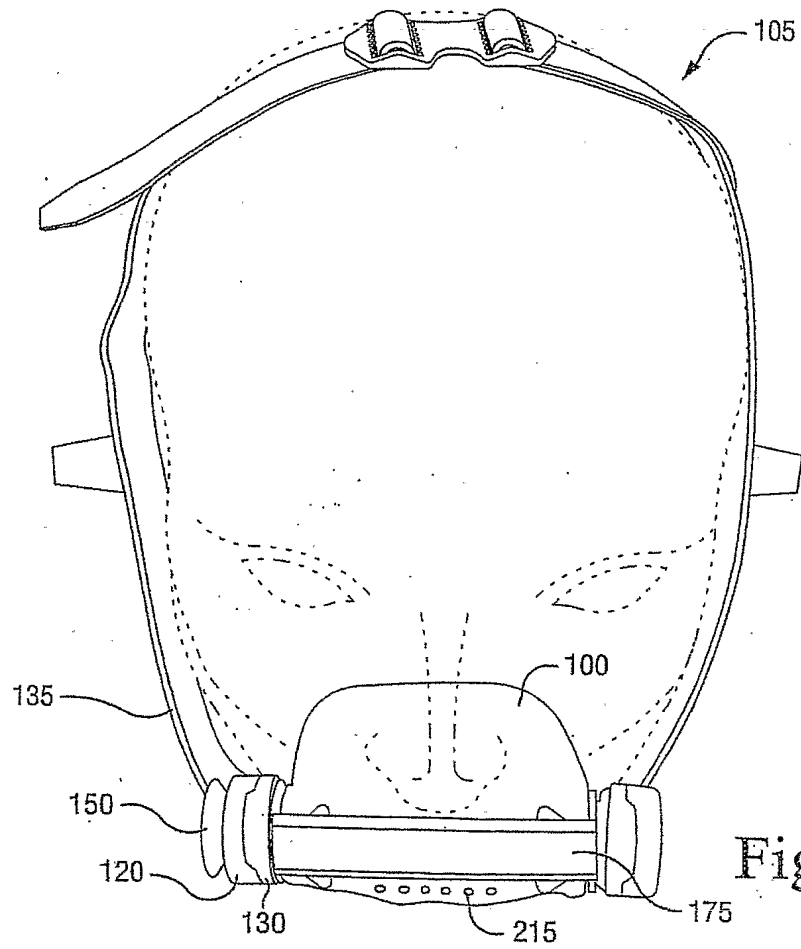


Fig. 11

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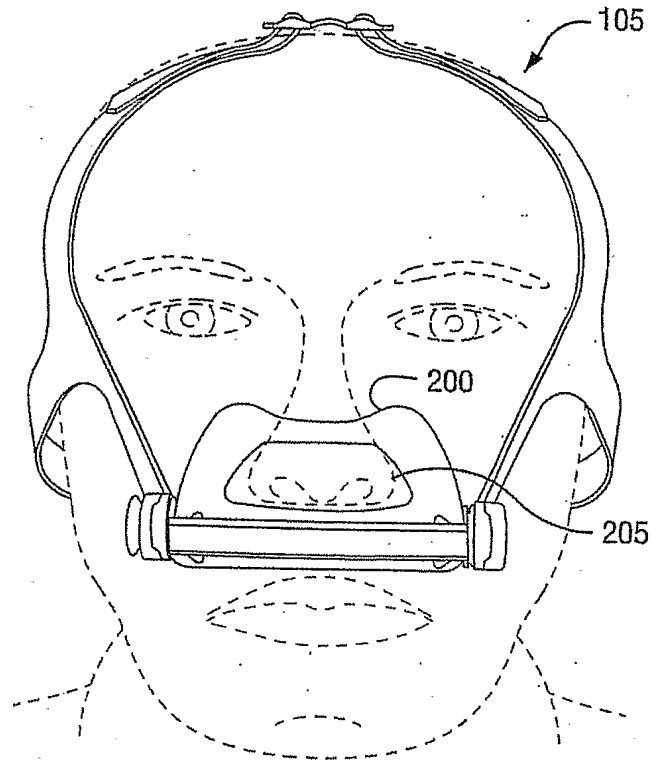


Fig. 12

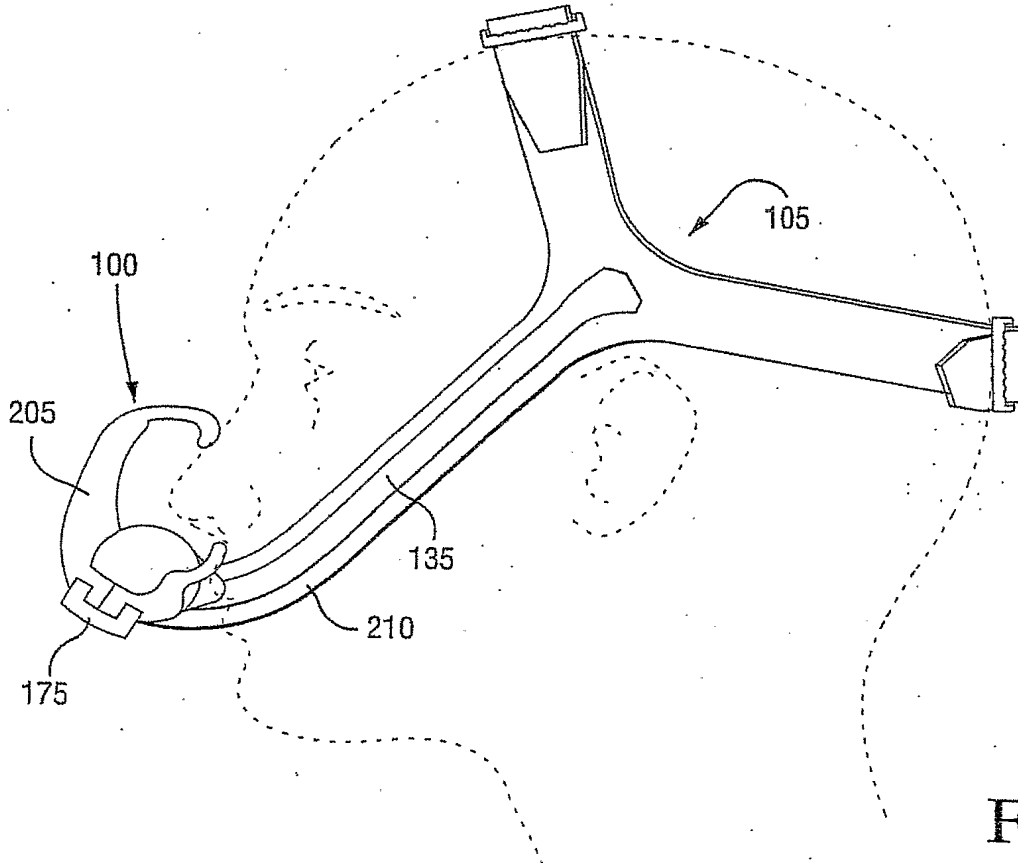


Fig. 13

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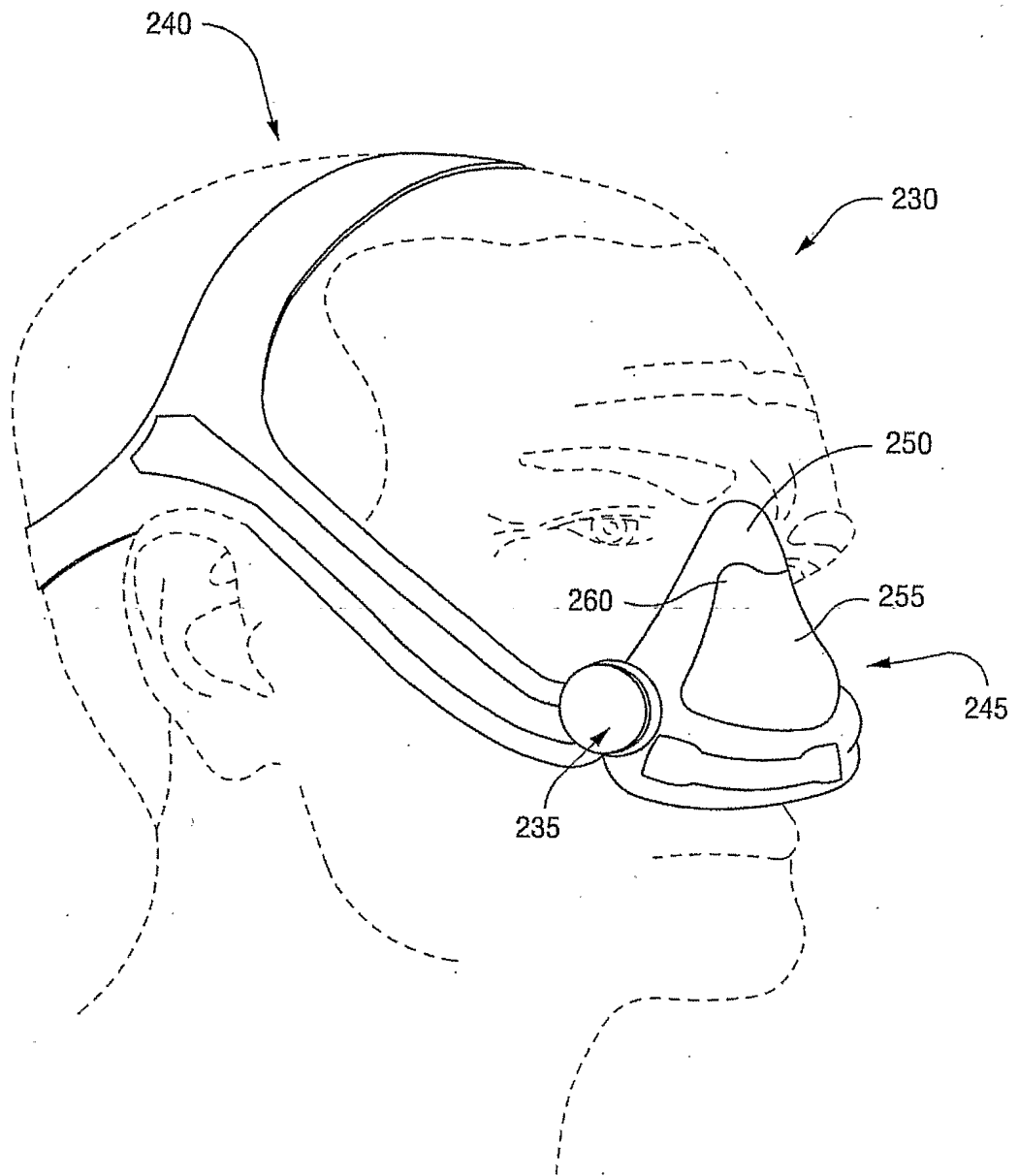


Fig. 14

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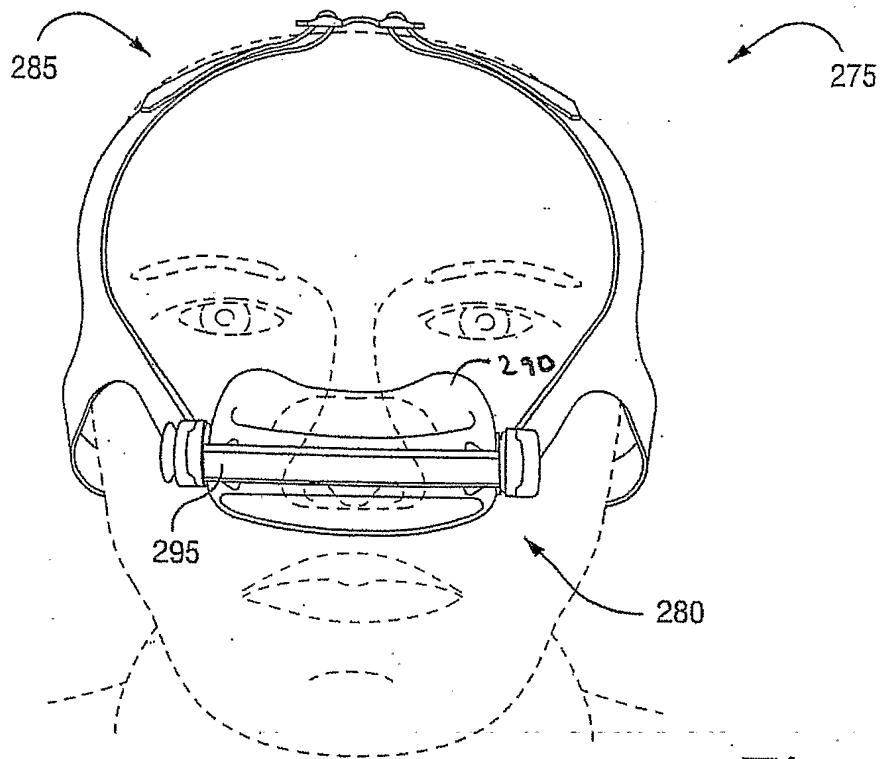


Fig. 15

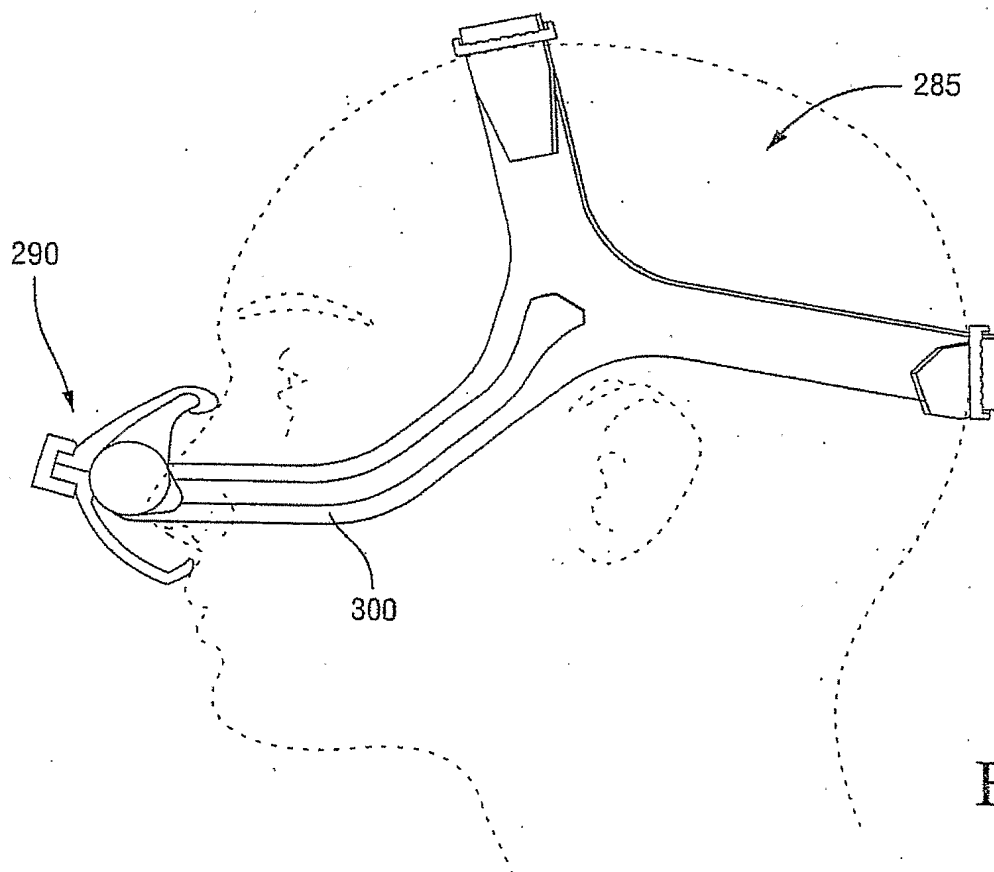
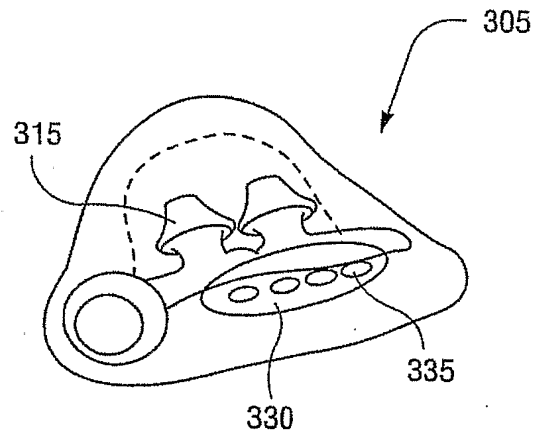
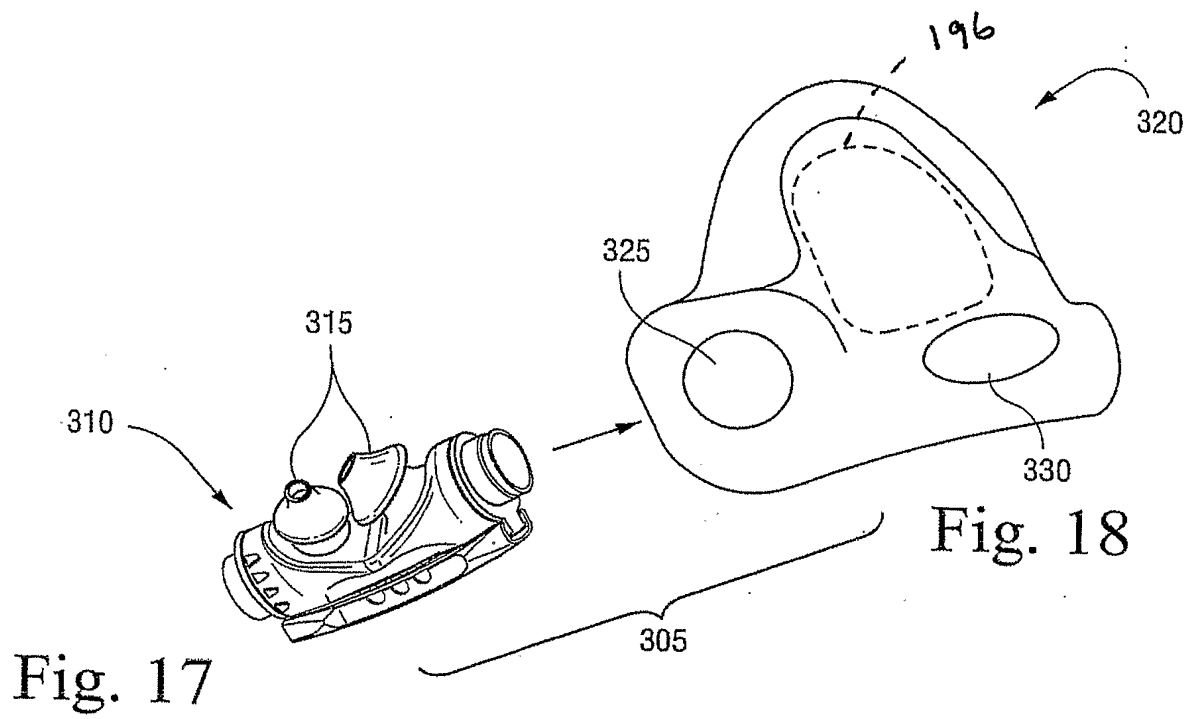


Fig. 16

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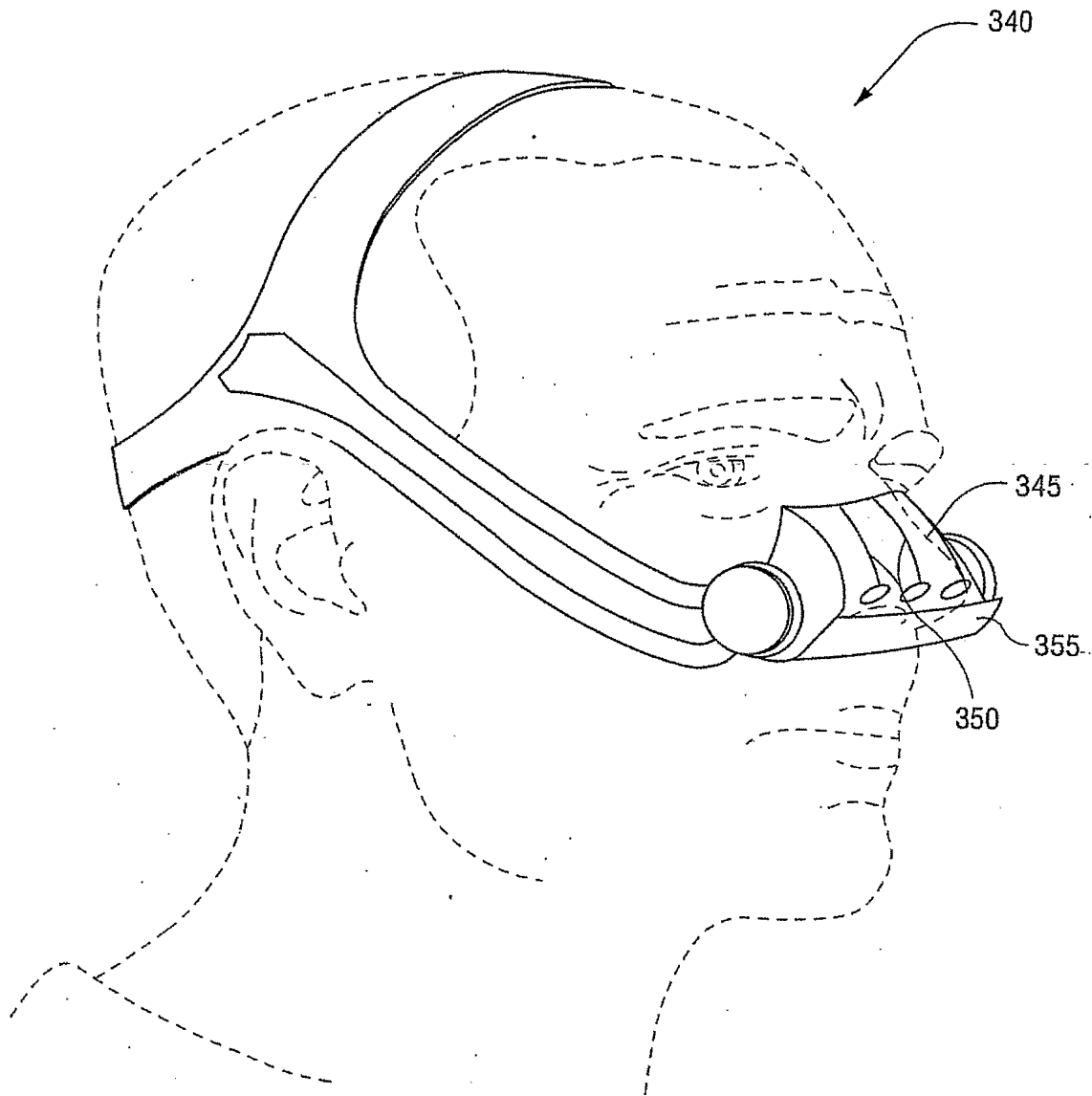


Fig. 20

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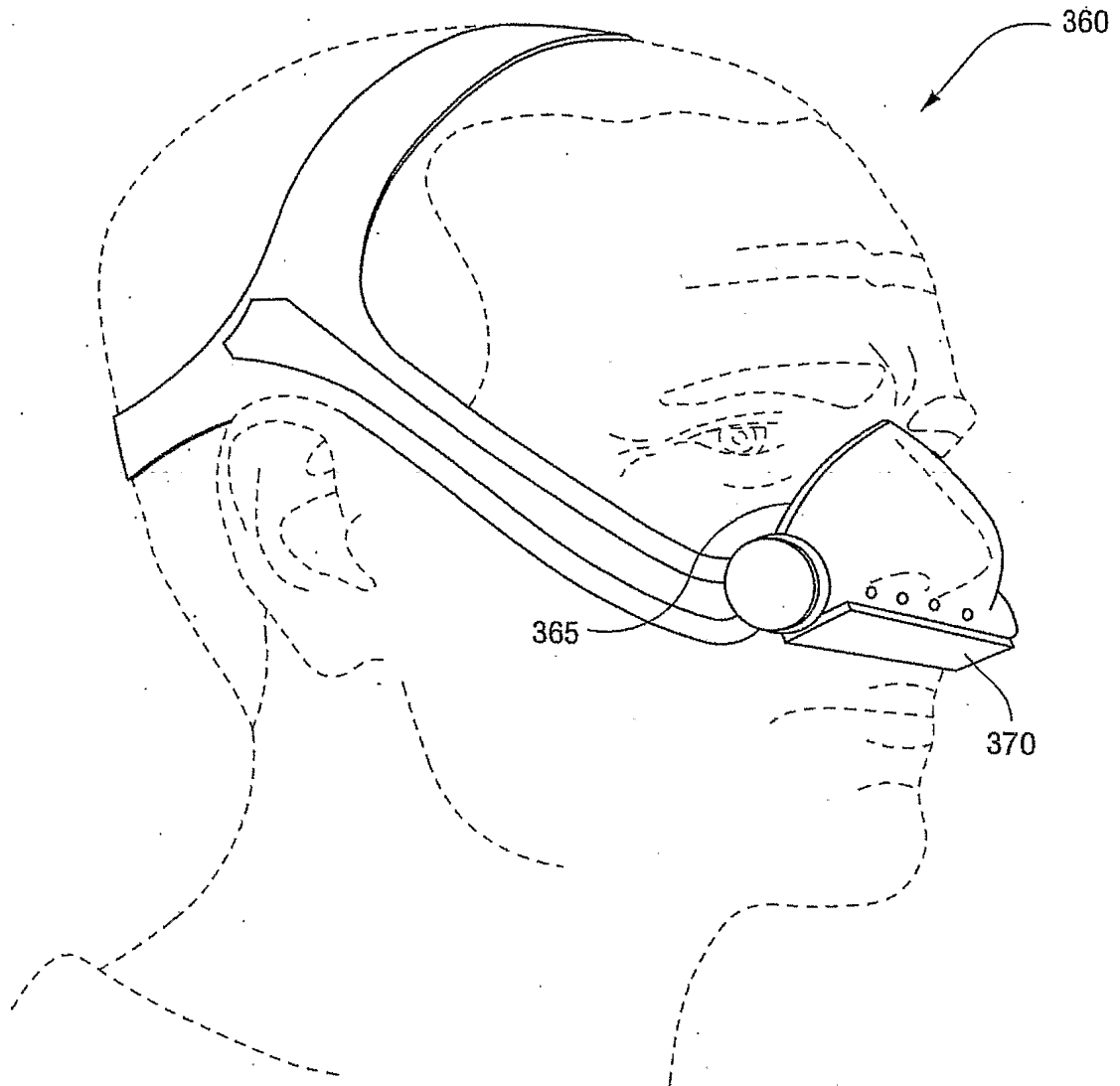


Fig. 21

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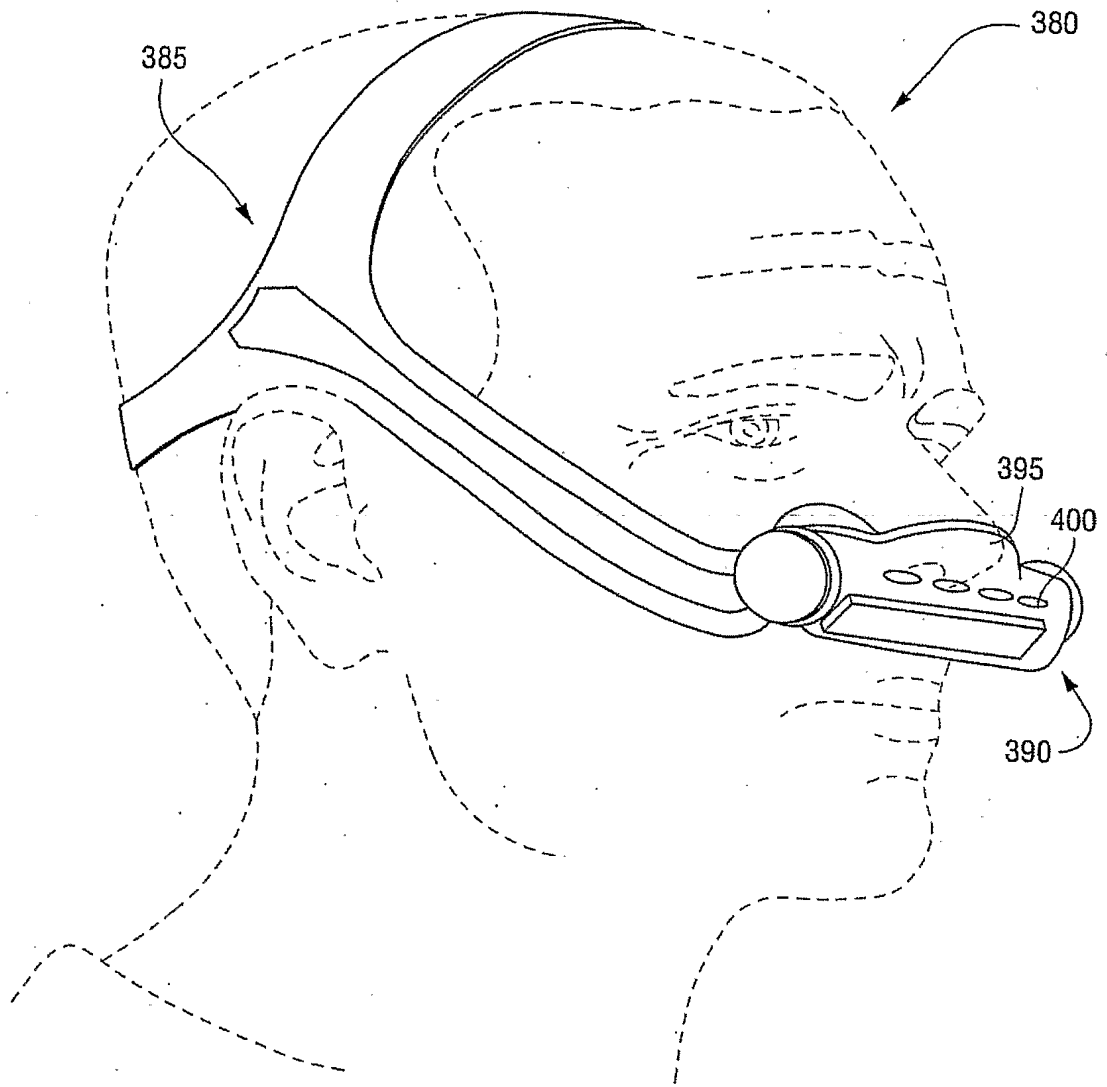


Fig. 22



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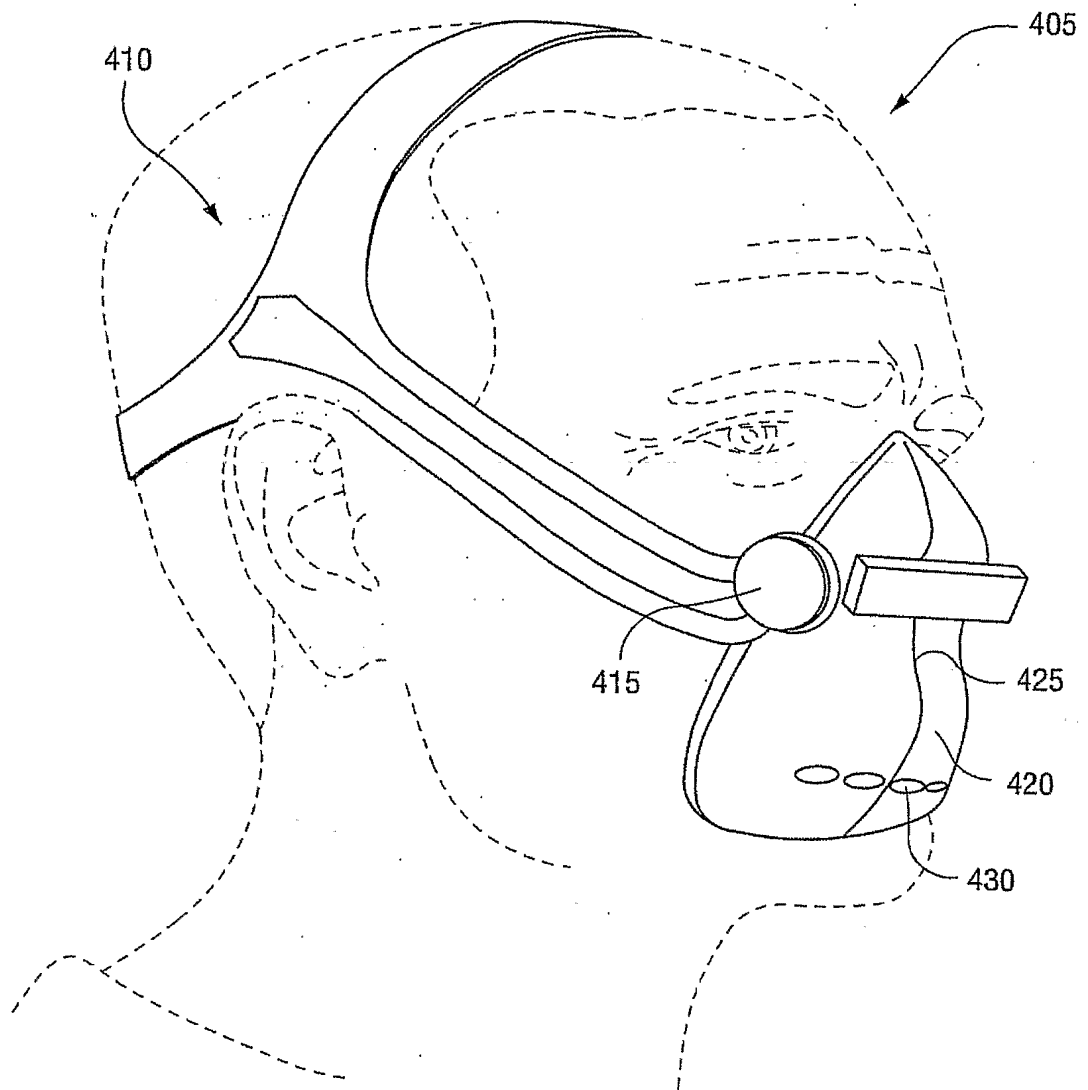


Fig. 23

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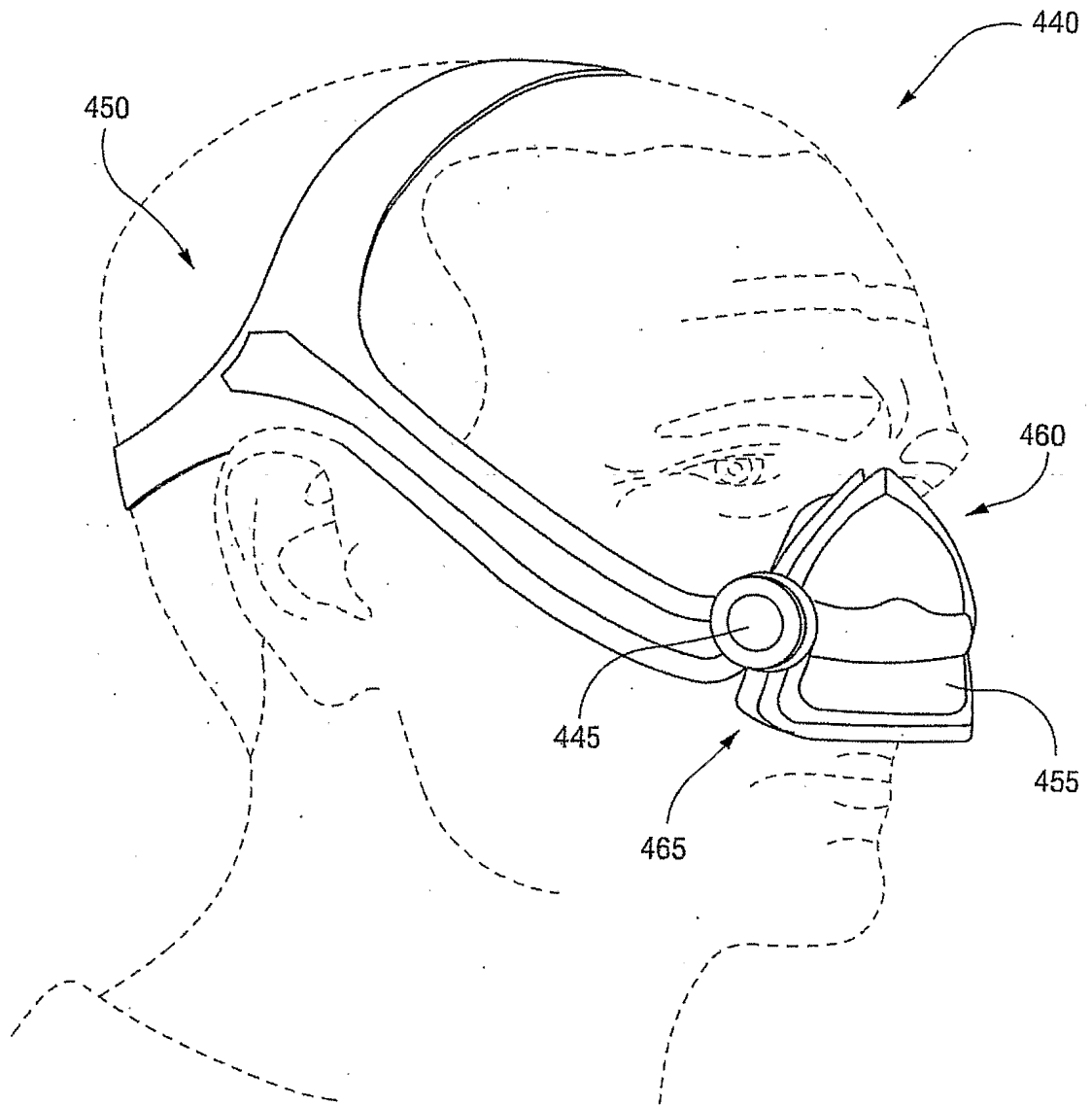


Fig. 24

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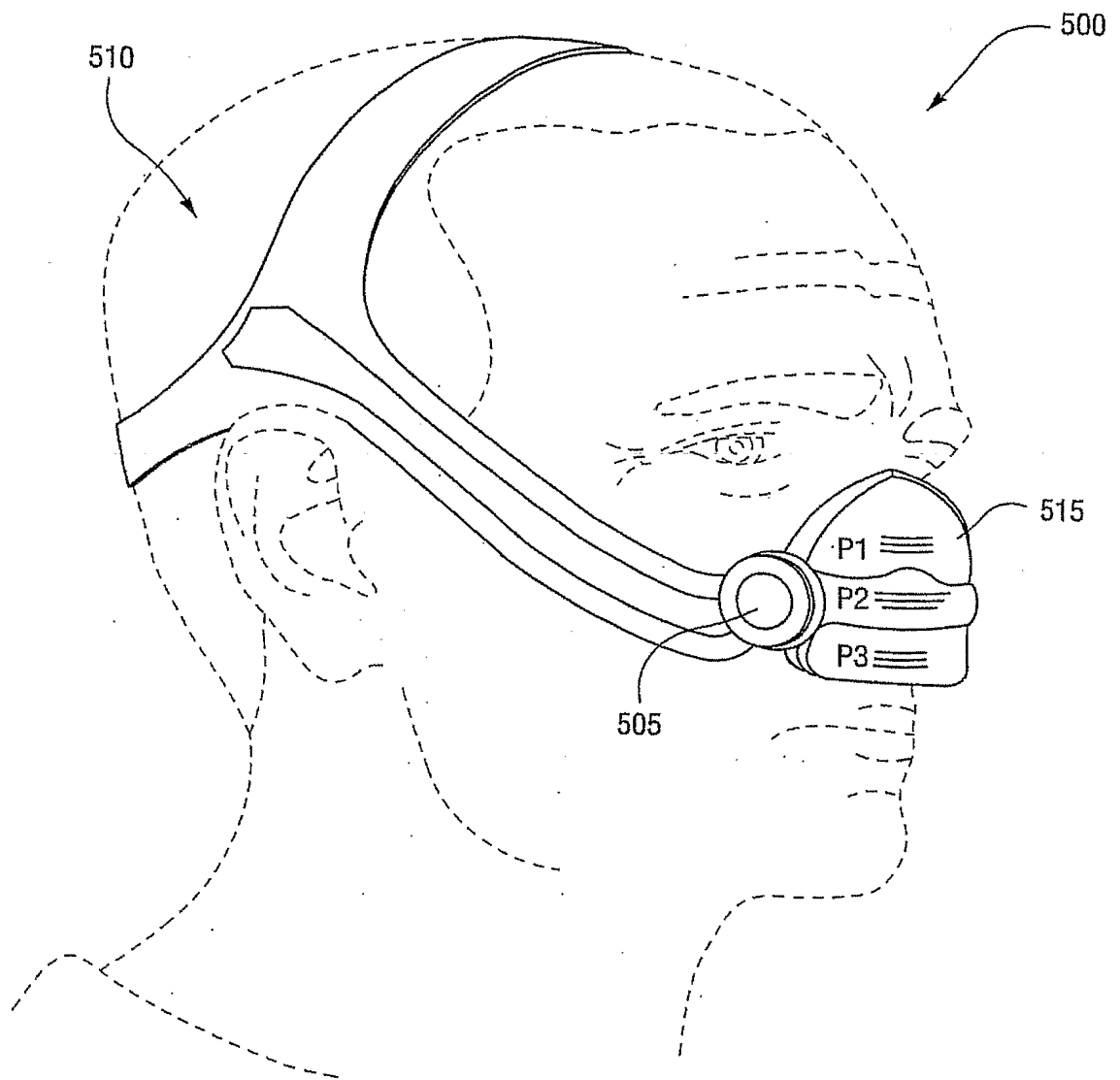


Fig. 25

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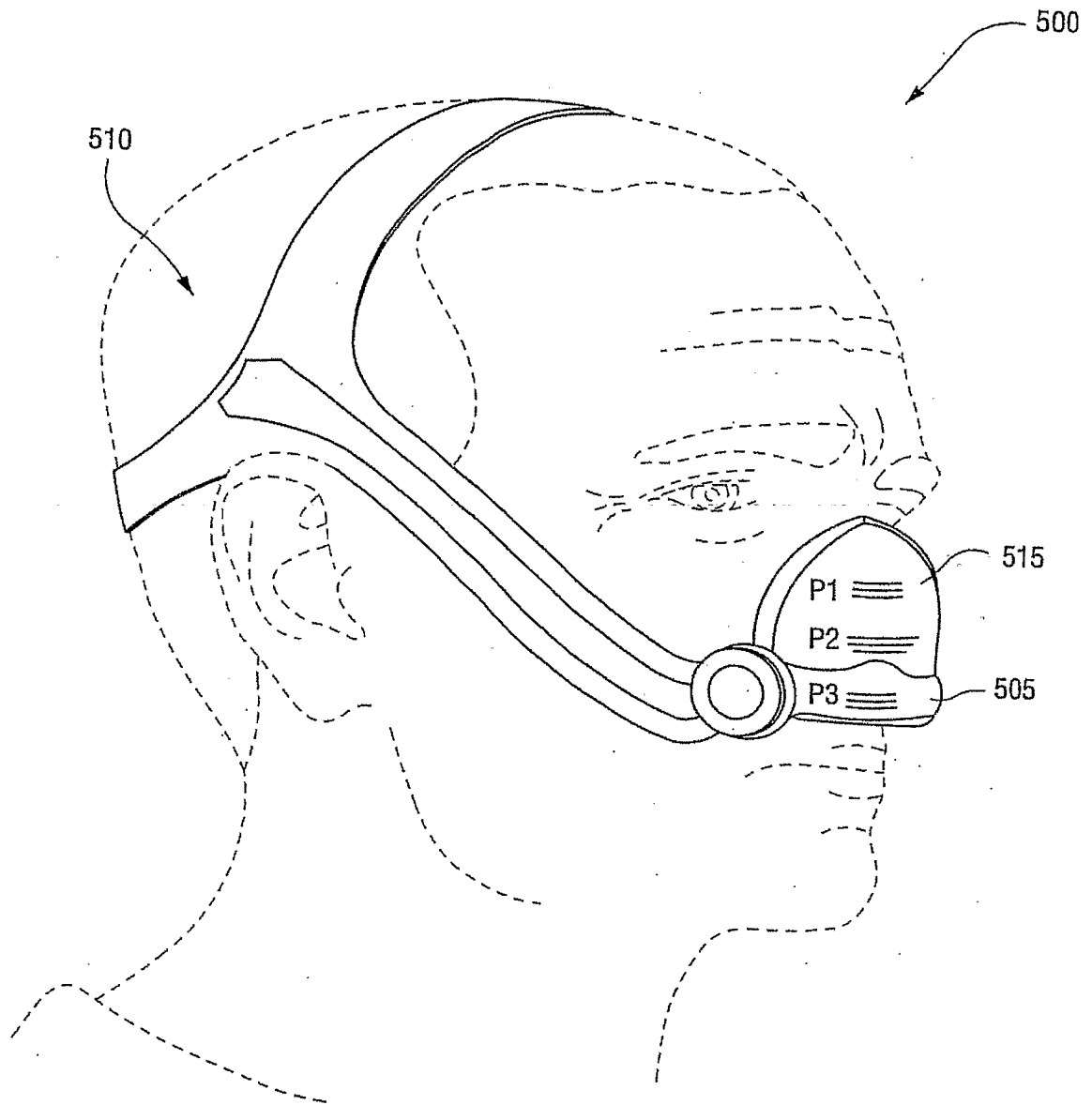


Fig. 26

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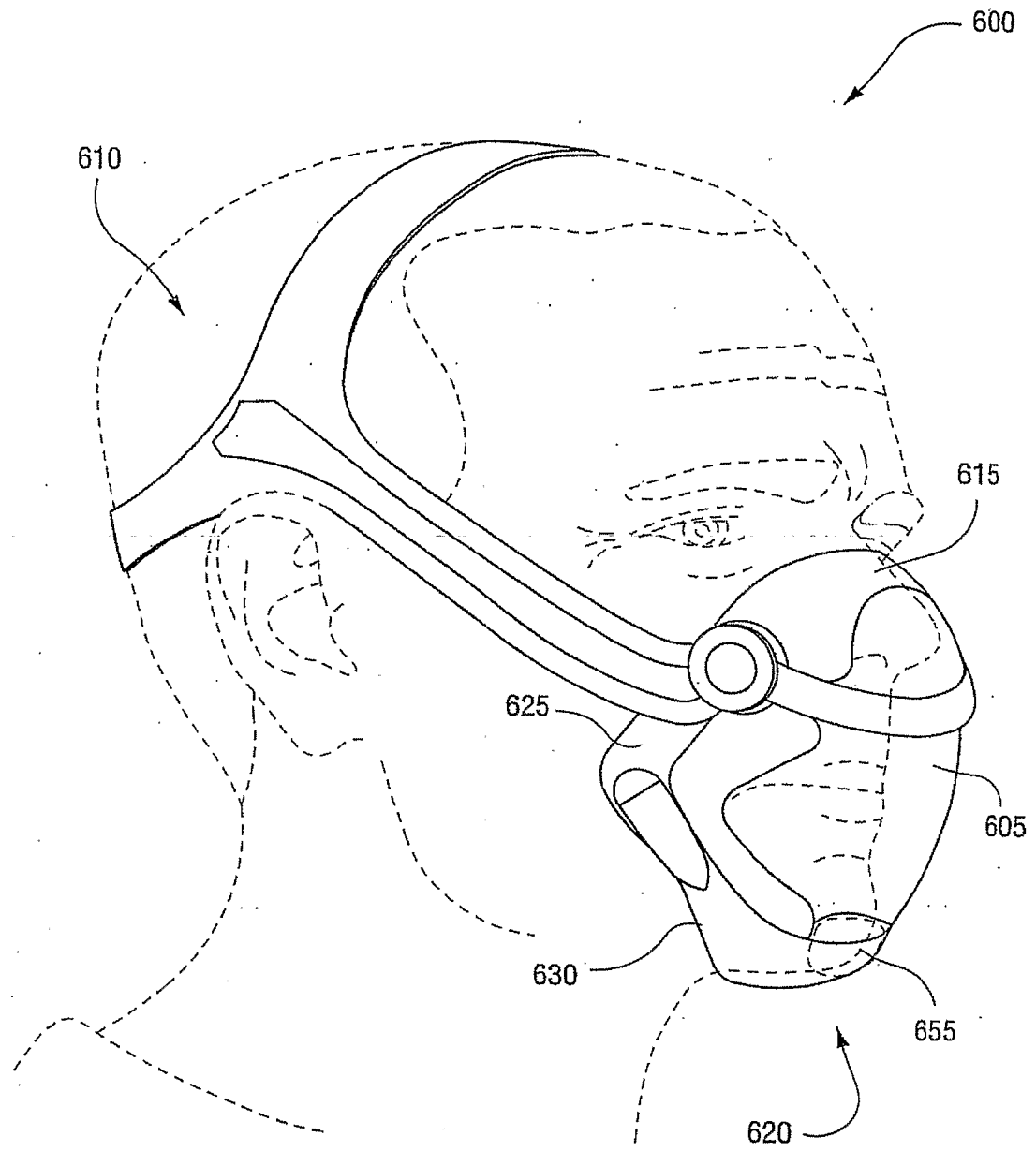


Fig. 27

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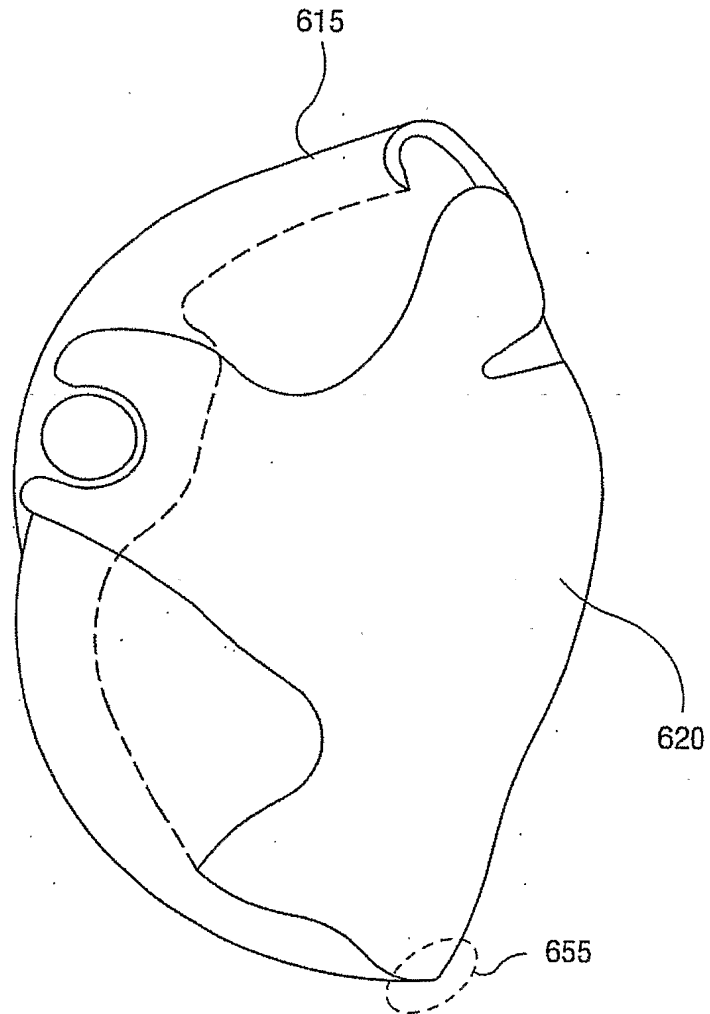


Fig. 28

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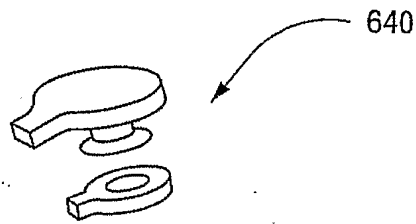


Fig. 29

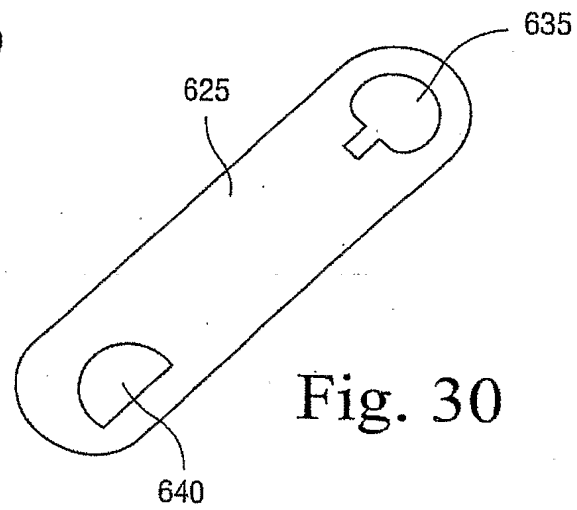


Fig. 30

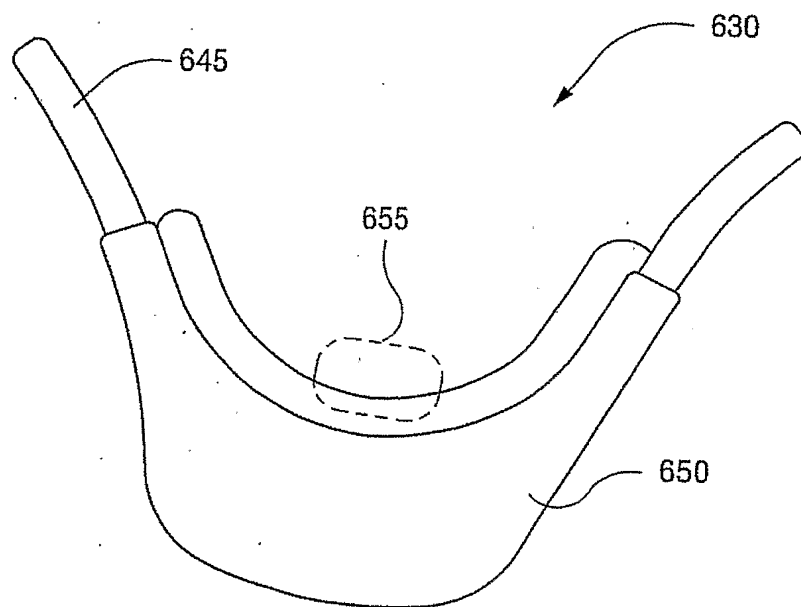


Fig. 31

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001570

## A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

**A61M 16/06** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI and IPC Mark A61M and keywords: mask and second and cushion and similar terms.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X         | US 2003/0196658 A1 (GING et al.) 23 October 2003<br>Paragraphs 228 and 229         | 1,2,13,14,41,<br>42   |
| P,X       | WO 2005/123166 A1 (RESMED LIMITED) 29 December 2005<br>Paragraphs 98 to 102        | 1,2,13,14,41,<br>42   |
| A         | US 6615832 B1 (CHEN) 9 September 2003<br>Whole document                            |                       |
| A         | US 5419317 A (BLASDELL et al.) 30 May 1995<br>Whole document                       |                       |



Further documents are listed in the continuation of Box C



See patent family annex

|   |  |
|---|--|
| * Special categories of cited documents:  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |
| "E" earlier application or patent but published on or after the international filing date   | "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | "&" document member of the same patent family  |
| "O" document referring to an oral disclosure, use, exhibition or other means  |  |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |

Date of the actual completion of the international search  
05 January 2007

Date of mailing of the international search report  
8 JAN 2007

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**Supplemental Box**

(To be used when the space in any of Boxes I to VIII is not sufficient)

**Continuation of Box No: III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 14, 41 and 42 directed to a mask system comprising first and second cushion components and a common frame assembly. It is considered that two cushion components comprise a first distinguishing feature.
- Claims 15 to 21 directed to a mask with a cushion component having a main wall with a stiffening portion. It is considered that the stiffening portion comprises a second distinguishing feature.
- Claims 22 and 23 directed to a mask assembly with a frame and a cushion, wherein the frame is positioned between the user's nose and upper lip. It is considered that the frame position comprises a third distinguishing feature.
- Claims 24 to 26 directed to a mask with a cushion component that engages the user's nose, wherein the cushion includes a nose height adjusting member. It is considered that the nose height adjusting member comprises a fourth distinguishing feature.
- Claims 27 to 33 directed to a mask with a frame and a cushion, wherein the position of the cushion relative to the frame is adjustable. It is considered that this adjustment comprises a fifth distinguishing feature.
- Claims 34 to 36 directed to a mask assembly with a chin strap. It is considered that the chin strap comprises a sixth distinguishing feature.
- Claims 37 to 40 directed to a mask assembly comprising a cushion component and a supplemental cushion component. It is considered that the supplemental cushion comprises a seventh distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/001570

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1 - 14, 41, 42

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

### Information on patent family members

**PCT/AU2006/001570**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in<br>Search Report   |            |     |            | Patent Family Member |            |    |            |
|---|------------|-----|------------|----------------------|------------|----|------------|
| US  | 2003196658 | AU  | 2003203830 | AU                   | 2003203832 | AU | 2003203833 |
|   |            | AU  | 2003203835 | AU                   | 2003203836 | AU | 2003218898 |
|   |            | CN  | 1623609    | CN                   | 1623610    | CN | 1623611    |
|   |            | CN  | 1628869    | CN                   | 1628870    | EP | 1356841    |
|   |            | EP  | 1356842    | EP                   | 1356843    | EP | 1356844    |
|   |            | EP  | 1360971    | JP                   | 2004000570 | JP | 2004000571 |
|   |            | JP  | 2004000572 | JP                   | 2004000573 | JP | 2004000574 |
|   |            | US  | 6907882    | US                   | 7047972    | US | 2003196655 |
|   |            | US  | 2003196656 | US                   | 2003196657 | US | 2003196662 |
|   |            | US  | 2005155604 | US                   | 2005199241 | US | 2006162729 |
|   |            | US  | 2006272645 | WO                   | 03090827   | WO | 2006096924 |
| WO  | 2005123166 | NIL |            |                      |            |    |            |
| US  | 6615832    | NIL |            |                      |            |    |            |
| US  | 5419317    | US  | 5109839    | US                   | 5311862    |    |            |
| Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001. |            |     |            |                      |            |    |            |
| END OF ANNEX  |            |     |            |                      |            |    |            |